NHS

National Treatment Agency
for Substance Misuse

Clinical governance in drug treatment

A good practice guide for providers and commissioners

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The National Treatment Agency for Substance Misuse

The National Treatment Agency for Substance Misuse (NTA) is a special health authority within the NHS, established by Government in 2001, to improve the availability, capacity and effectiveness of treatment for drug misuse in England.

The NTA works in partnership with national, regional and local agencies to:

- Ensure the efficient use of public funding to support effective, appropriate and accessible local services
- Promote evidence-based and coordinated practice, by distilling and disseminating best practice
- Improve performance by developing standards for treatment, promoting user and carer involvement, and expanding and developing the drug treatment workforce
- Monitor and develop the effectiveness of treatment.

The NTA has led the successful delivery of the Department of Health's targets to:

- Double the number of people in treatment between 1998 and 2008
- Increase the percentage of those successfully completing or appropriately continuing treatment year on year.

It is now in the front-line of a cross-Government drive to reduce the harm caused by drugs and its task is to improve the quality of treatment in order to maximise the benefit to individuals, families and communities.

Going forward, the NTA will be judged against its ability to deliver better treatment and better treatment outcomes for the diverse range of people who need it.

Reader information

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Clinical governance

Clinical governance is a multi-faceted framework and its full implementation in any organisation involved in commissioning or providing drug misuse treatment can be a complex process and may take time.

Organisations with little or no clinical governance in place should make a start. Other organisations can use this document to consider how to improve further. It can be relatively simple to get the basics right and then progressively to build more effective systems.

Where can you start?

- Providers – appoint a clinical governance lead if not already in place
- Partnerships – consider the need for a partnership-wide lead
- Providers, commissioners or partnerships – clarify responsibilities for clinical governance
- Providers – audit existing clinical governance practice and consider the priorities for safety and quality assurance
- Providers and commissioners – establish priority local clinical governance mechanisms and explore making use of any other such mechanisms in other parts of the organisation or already established in other local organisations
- Partnerships – identify the effective clinical governance mechanisms already in use locally (usually in PCTs or mental health trusts) and help drive adoption of suitable mechanisms in services without these
- Partnerships – ensure the existence of, and participation by stakeholders in, a multi-agency group: with a remit to consider clinical governance for the drug treatment system as a whole and concerning the sharing of information and good practice
- Providers, commissioners or partnerships – consider the timetables of external assurance mechanisms (such as NTA treatment planning) and how these can mesh with local clinical governance processes
- Providers – consider the audit tools already available for drug treatment, for example, the NTA's guide to Auditing Drug Treatment (NTA, 2008a) and NICE's audit tools for its drug misuse 'Technology Appraisals' and 'Clinical Guidelines' (available at www.nice.org.uk).

1 Executive summary

1.1 Introduction

This document aims to advise on and support the effective implementation of clinical governance for all drug treatment providers, across all tiers, whether delivering health or social care, and whether public or independent (private or voluntary sector). It is intended as a guide for clinicians, commissioners and service managers in both the NHS and independent/non-statutory sector.

Clinical governance is an established system in the NHS and independent healthcare sector to deliver and demonstrate that the quality and safety of its services are of a high standard that is continually improving. However, this approach is also relevant to other healthcare providers and to providers of social care, where it may currently be referred to as practice governance, care governance or quality governance. For most drug treatment services, implementation of clinical governance is already a statutory or contractual obligation, and a consistent focus on clinical governance by all providers and commissioners of drug treatment will ensure higher quality services for drug misusers.

The general principles of clinical governance described are equally applicable to those treating adults and young people, although there will be significant differences in some of the elements covered in relation to young people. Issues such as safeguarding and informed consent will receive special attention in local governance arrangements for children.

A clear focus on supporting services to improve their implementation of clinical governance is important because:

- The wealth of guidance on evidence-based clinical practice, published in 2007 and including Drug Misuse and Dependence: UK Guidelines for Clinical Management, and the suite of NICE technology appraisals and clinical guidelines on drug misuse, calls for good clinical governance
- Clinical governance has been found to be inconsistently implemented and applied in healthcare settings, especially in drug treatment and in primary care
- Clinical governance is complex in the drug treatment sector, which crosses health, social care and criminal justice, and organisational boundaries.

Improvement in clinical governance frameworks for drug treatment and for service providers is an incremental process. This guide is aimed at assisting with realistic improvements. It is not intended as a one-size-fits-all blueprint for delivery. Some large organisations will already have access to highly developed support systems. Other organisations will not have this but will wish to improve their current support structure. Provider groups covering local drug partnership areas present an opportunity for providers to enhance clinical governance across the partnership and to consider sharing or utilisation of resources.

Clinical governance is a process, made up of a large number of elements. For many of these there are a range of criteria or recognised standards of good practice that can be used in audit and benchmarking. In the NHS the current key framework incorporating relevant criteria for many aspects of clinical governance is Standards for Better Health. While such a generic ‘standards’ framework can provide the basis for choosing criteria for auditing clinical governance of drug treatment, in practice, in order to address specific drug misuse treatment and care priorities, it needs to be supplemented with other guidance and criteria that are specific to drug misuse. Examples include national drug misuse clinical guidance as well as explicit criteria drawn from recent NTA and Healthcare Commission reviews of drug

treatment and from other relevant areas of care and treatment, including statutory standards for some providers of health and social care.

In 2009 a new integrated health and social care regulator, the Care Quality Commission, began work to register all health and social care service providers and operate an integrated, risk-based system of regulation to ensure that providers of health and social care services in the private or public sector meet essential levels of quality and safety. A new set of registration requirements will effectively replace the core standards within Standards for Better Health (for NHS healthcare) and the National Minimum Standards and Regulations (for social care and independent healthcare) for the purposes of regulation, although Standards for Better Health may continue to be used in health services as a framework for clinical governance.

1.2 What clinical governance covers

Clinical governance is usually thought of as a framework containing a number of domains to be addressed that impact on the quality and safety of care.

Some elements within these domains are generic to all health and social care, for example, dealing with untoward incidents, and ensuring that staff are competent to do their jobs and are adequately trained and supervised.

Focusing on drug treatment, there will then be particular priorities and more detailed elements within these domains that relate specifically to this area of care. So, for example:

- Within the safety domain, local inquiry procedures in cases of drug related deaths can be an important component of the investigation of untoward incidents, and policies to address needle-stick injuries are a relevant element of client safety standards
- Within the clinical effectiveness domain, staff competence includes a doctor's or a nurse's or a drugs worker's competencies to provide specific drug treatments and will also extend to requirements for continuing professional development and clinical supervision and other mechanisms for staff development.

1.3 Clinical governance components

Clinical governance components include lines of responsibility and accountability, quality improvement activities, policies that manage risk, and procedures to identify and remedy poor performance. Some organisations and individuals are directly and statutorily accountable for elements of clinical governance but all have a general responsibility to engage in activities that improve client safety and treatment effectiveness.

Clinical audit is a key quality improvement activity driving and supporting clinical governance and is in need of improvement in many drug services. It is often most effective delivered within an 'audit cycle' that involves determining the standards or criteria for the audit, monitoring performance against the standards or criteria, and following a process for taking further actions to improve future outcomes, followed by further review to identify progress.

Most service audits will be developed from locally-driven priorities. However, some audits may be requested from outside of the provider organisation, as in, for example, recent NTA and Healthcare Commission service reviews.

1.4 Roles, responsibilities and assurance

All providers delivering health or social care – whether NHS, local authority, criminal justice or independent sector – and commissioners of such care, have a responsibility to ensure effective clinical governance in drug treatment services. In many cases, carrying out these responsibilities will arise from a statutory and contractual (i.e. for NHS and NHS-

commissioned services) or just a contractual (for drug partnership and other non-NHS commissioned services) requirement. In others, these are not statutory or contractual obligations but are clearly recognised as best practice in providing assurance of the quality of care. The responsibilities can be summarised as follows:

- **Local drug partnerships** take the lead on planning and commissioning treatment services in their area. They take a lead in ensuring that appropriate local systems for clinical governance are in place and that clinical governance is embedded within the services they commission. However, the statutory responsibility for clinical governance will usually fall to some of their member organisations.
- **Primary care trusts** are required to ensure that contracts fit the requirements of Standards for Better Health and will need mechanisms in place to monitor compliance. NTA/Healthcare Commission substance misuse criteria have also provided a key driver of improvements in quality. When PCTs commission care within the NHS, there will also be clinical governance responsibilities for the NHS provider. However, the PCT's responsibilities for standards-compliant care are especially pertinent when commissioning voluntary sector services, when the PCT commissioner has a statutory responsibility for ensuring good clinical governance. Further information to support effective commissioning will be published by the NTA in 2009. **Local commissioning partnerships, and PCT commissioners especially,** may take the lead in requiring services to implement or improve clinical governance, by building these requirements into service level agreements and ensuring compliance through performance management.
- **Mental health and foundation trust drug treatment services** are usually required to take part in their trust clinical governance system and would normally be expected to designate a clinical governance lead.
- **Primary care services** must take part in the local NHS clinical governance system. They are required to designate a clinical governance lead in every practice and participate in clinical governance activity across the PCT.
- **Non-statutory sector providers** will want to carry out elements of clinical governance as good practice but most will also have responsibilities depending on how they are commissioned and the services they provide. These include:
    - Those registered as independent healthcare providers with the Care Quality Commission, under legacy arrangements from the Healthcare Commission, have a statutory requirement to assure themselves against the Independent Healthcare Minimum Standards. By 2010 they will be expected to assure themselves against new registration requirements.
    - Those commissioned by PCTs will be accountable to them for clinical governance, and would normally be assured against Standards for Better Health (or in future by their replacement)
    - Registered care homes that formerly operated within the regulation of the Commission for Social Care Inspection (CSCI) were required to meet standards for systems of governance, although these were not called clinical governance. These arrangements continue in 2009 under the Care Quality Commission but, in 2010, will be superseded by new registration requirements.
    - Services that are not regulated by the Care Quality Commission (and formerly Healthcare Commission and CSCI) or other mechanisms will also normally be expected to deliver services in line with national standards and guidance. Services funded through Supporting People will be regularly reviewed by local Supporting People teams to ensure they meet standards laid down by central government. Other services may be contractually required to provide assurance against other standards, for example local authority Best Value Performance Indicators. Clinical governance is good practice for drug treatment providers whether or not it is required by contracts.

- **Services that cover multiple geographical areas or a number of different treatment modalities** may be required to meet the clinical governance requirements of multiple commissioners.
- **Prison healthcare** commissioned jointly by the PCT and prison – including drug treatment programmes – will be subject to clinical governance requirements, as for other healthcare commissioned for NHS patients. Drug treatment that is directly commissioned by the prison service or private prisons – including CARATs, accredited cognitive behavioural programmes and therapeutic community programmes – will fall outside these requirements. NOMS Interventions and Substance Misuse Group, prison healthcare managers and governors (or directors of contracted-out prisons), as appropriate, can all assure quality and safety by ensuring that effective clinical governance is in place for these programmes.

  NB The Prison Drug Treatment Strategy Review now underway could result in significant changes to the commissioning and delivery of prison based drug treatment, and the continuity of care of drug-using offenders on release, in which case the exact details of clinical governance arrangements and responsibilities might also be affected.
- **Community criminal justice drug treatment** covers clinical treatment for drug misusing offenders provided by services already providing treatment to other drug misusers (in which case it will usually be subject to the same requirements as other healthcare for NHS patients) and psychosocial interventions commissioned or provided by the probation services, which may benefit from additional clinical governance mechanisms.

It is important to note that many clinical staff (doctors, nurses, clinical psychologists and pharmacists) have a professional duty to participate in clinical governance systems and activities, in whichever type of service they are based. They will need to ensure that the requirements on them as professionals are reflected appropriately in organisational arrangements.

In addition to these individual and organisational responsibilities, clinical governance processes may be important across organisational and professional boundaries. Effective clinical governance at the interfaces is especially important and this may be usefully supported by a partnership-wide clinical governance group.

1.5 Service users and carers

Service users play a number of critical roles in clinical governance. As well as being the recipients of the safe and effective care that is the focus of clinical governance they may also have roles in:

- The active planning and delivery of their own treatment
- The monitoring, development, design and planning of local services
- Providing services themselves.

Service users may need support, perhaps including training, to function effectively in these roles, especially if they are involved in more than one role, where there may be the potential for conflict.

1.6 Implementing clinical governance

Fully-developed clinical governance can be complex. Organisations may need to start with a simple framework and build up to a more developed system over a number of years. Providers and commissioners intending to deliver safe and effective care and who have recognised the value and importance of clinical governance need at least to start the implementation process.

Implementation will vary depending on the size and nature of the organisation. A large mental health or foundation trust or PCT may have a clinical governance team and committees dedicated to different aspects of clinical governance. A small voluntary organisation may only need to identify a clinical governance lead and ensure that a modest programme of clinical governance activities is carried out.

The drug treatment sector has the opportunity to share knowledge and experience between partnerships and provider services. The current range of treatment provider groups allow for such exchange and partnerships may wish to consider supporting such initiatives.

2 Introduction

2.1 Key points

- Clinical governance describes a systematic approach to monitoring and improving the quality, safety and effectiveness of clinical interventions
- Clinical governance is relevant to, and provides benefits for, all individuals and organisations providing and commissioning treatment for drug misusers
- Clinical governance is a statutory requirement for many organisations involved in delivering drug treatment
- Drug treatment cuts across many organisational boundaries and clinical governance places different demands on the different organisations involved
- The use and quality of clinical governance in the drug treatment sector currently vary widely and there are opportunities for greater consistency, and for developing rigorous and high quality clinical governance across the sector.

Clinical governance – what's in it for me?

"The more people grasp it the more they want to be involved. This is exciting - as chair of a big committee, it is akin to conducting an orchestra of accomplished players. … The cardinal benefit has been the ability to form a culture that feels good. Staff [from all involved services] know that they belong to this Directorate. It has removed any sense of 'poorer sister borough' and allowed for the expression of local need as well as local qualities."

Central and North West London Mental Health Trust (William Shanahan, medical director and chair, clinical governance committee)

"The service itself benefits from the structured approach to its quality initiatives, being able to identify policy gaps, demonstrate delivery of clinical quality already established and a feeling of improved integration with the local NHS."

Lifeline Kirklees (Bridget Hughes, service manager)

"Now that staff are engaging with the process teams will automatically come up with service improvement initiatives rather than these being imposed by managers. … A massive vehicle for change, very exciting."

Cygnet Heathcare (Malcolm Carr, director of clinical services)

"Benefits to the organisation include … involvement of all staff, which is empowering to more junior staff and allows a bottom-up approach."

Addaction

2.2 Aim of this document

The aim of this document is to advise on the effective implementation of clinical governance among all drug treatment providers, across all tiers, whether delivering health or social care, whether public or independent (private or voluntary sector), and whether with adults or young people. The document:

- Clarifies and defines what is meant by clinical governance and its component parts

- Describes treatment providers' and commissioners' roles and responsibilities regarding clinical governance
- Describes senior clinicians' and managers' roles and responsibilities for clinical governance, and aims to raise all service provider staff's awareness of the opportunities for them to contribute to clinical governance processes as part of their normal professional practise.

2.3 Who the guide is for

The guide is aimed at clinicians and at service managers, in both the NHS and independent/non-statutory sectors, and at commissioners. A clinician in this context is defined as anyone who directly provides pharmacological or psychosocial treatment to drug misusers and therefore includes doctors, nurses, pharmacists, psychologists and most drug workers.

A draft guide was developed by the NTA, advised informally by a group of experts and stakeholders. Following public consultation on the draft this final version was developed.

The general principles of clinical governance described are equally applicable to those treating adults and young people, although there will be significant differences in some of the elements covered in relation to young people's substance misuse services in order to ensure that the implications of the Children Act 1989 and 2004, the Children's National Service Framework and assessment arrangements for children's services are taken into account.

2.4 What is clinical governance?

Clinical governance is relevant to all individuals and organisations providing and commissioning treatment for drug misusers, even where their interventions might not be considered as 'clinical'. In these settings it may be known as practice, service, care or quality governance but this document uses the single, widely-accepted term of clinical governance. This reflects the broader definition of 'clinical' adopted by the 2007 Clinical Guidelines (DH and devolved administrations, 2007), in which 'clinicians' covers the wide range of individuals providing treatment for drug misusers.

'(Clinical governance is) a framework through which … organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish' DH 1998

The key elements in this definition of clinical governance are:

- Framework – The various activities included in clinical governance need to be set within a framework that enables assurance for all aspects of clinical activity in a comprehensive and systematic way.
- Accountability – Public and independent sector health and social care organisations have a statutory duty to assure themselves on the quality of care they provide. Regulatory authorities ensure accountability for clinical governance. A structured accountability framework running right through the organisation ensures that everyone takes responsibility for clinical governance.
- Quality – Clinical governance should aim to ensure that treatment is safe, evidence-based, effective, cost-effective, available, accessible and equitable, and that delivers the best possible service user experience.
- Environment – A culture in which individuals and organisations can openly and honestly examine their own practice and take responsibility for change to achieve improvement. Requires a supportive no-blame ethos which focuses on systemic improvement.

Clinical governance describes a systematic approach to monitoring and improving the quality, safety and effectiveness of clinical interventions. There is no single task, structure or process that is clinical governance. Rather, it describes the totality of tasks, structures and processes implemented to improve the quality of treatment and care delivered to service users.

Most organisations will already be carrying out many of these tasks, will have many of these structures and will use many of these processes. So, clinical governance is not necessarily about doing anything new but about bringing existing quality assurance activities together and identifying any areas for future development.

Typically, clinical governance covers a range of general domains, often drawn from Standards for Better Health (DH, 2004a), whose domains are listed in table 1. These headings provide a checklist for delivering quality, but clinical governance is more than a list – it is the means by which quality is assured.

And for drug misuse, the headings may take on a different priority or a different focus than in other branches of health and social care. These will be determined by, for example:

- National drivers:
- Statutory requirements
- National performance targets
- National clinical guidance, including NICE guidance and Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH & devolved administrations, 2007)
- NTA/Healthcare Commission Service Review criteria.
- Local drivers:
- Commissioner priorities
- Organisational priorities
- Professional and clinical priorities.

These are described in more detail in chapter 3.

Domains for clinical governance

- Safety
- Clinical and cost effectiveness
- Governance
- Patient focus
- Accessible and responsive care
- Care environment and amenities
- Public health

Standards for Better Health, DH 2004a

Table 1. Domains for clinical governance

2.5 The benefits of clinical governance

Clinical governance can be a powerful tool for ensuring continuous quality improvement. It can also provide critical systems for avoiding untoward incidents or, where incidents have occurred, for ensuring that lessons are learned from them and promulgated throughout the organisation to prevent recurrence.

Provider organisations and service managers find that clinical governance can enable them to have confidence in the quality of the services they provide, and identify gaps they may not have considered. They also gain from the improved motivation of staff to deliver to a quality agenda, and from coordination of improvements through cyclical action planning, allowing realisation of a longer-term vision. In addition, clinical governance can deliver to service managers ready-made quality assurance evidence with which to make required reports to commissioners.

Commissioners can benefit from clinical governance by being able to evidence value for money in the services they commission, and by having the assurance reports they require in order to assure, in turn, national registration and inspection bodies. Strategic direction from commissioners can be implemented through clinical governance improvement cycles and action plans.

Although existing standards frameworks, clinical governance toolkits and audit checklists can be very helpful in getting started with implementation, and as an illustration of the clinical governance process, it is desirable that provider organisations, their staff and service users take ownership of the whole process by, for instance, devising their own standards frameworks and determining audit topics that are important to them, and that commissioners are involved in ensuring that clinical governance is prioritised and resourced, so that they can all experience the full benefits of clinical governance.

2.6 Why this guide is likely to be useful

2.6.1 Clinical governance is a statutory requirement for most organisations involved in delivering drug treatment

The Care Standards Act 2000 and the Health and Social Care (Community Health and Standards) Act 2003 established legal obligations for the entire healthcare sector and relevant parts of the social care sector to assure themselves annually on the quality of services they provide or commission. The Acts also put in place new regulatory authorities with powers to inspect health and social care, collate trusts' self-reports and report their findings annually to parliament. Clinical governance is now the established mechanism by which the government is assured on quality in clinical aspects of care.

During 2009/10, NHS providers, for the first time, will need to be registered under the Health and Social Care Act 2008.

Commissioner and provider organisations falling under the umbrella of the Acts are legally required to have clinical governance frameworks and processes in place, and to comply with one of the statutory standards frameworks. In 2009/10 the Care Quality Commission's review of NHS providers will replace the former Healthcare Commission's Annual Health Check.

Independent heath care and adult social care providers will continue to be registered under the Care Standards Act 2000 and compliance with registration will be reviewed by CQC in a similar way to previously.

From 2005 to 2008, the Healthcare Commission and NTA conducted annual reviews to assess against criteria for drug treatment. These took drug partnerships as the unit of assessment and so covered the vast majority of community drug treatment provision. In 2007/8, through joint working with CSCI, the review also assessed services providing Tier 4 interventions. In 2009/10, new arrangements will apply and the Care Quality Commission will include drug treatment in its ongoing assessment of overall treatment provision.

2.6.2 Clinical governance in drug treatment is patchy and inconsistent

There were indications in 2003 that commissioning for clinical governance had been poorly developed in PCTs (CGST and NatPaCT, 2003), and there may be particular issues with regard to independent providers, including primary care (NAO, 2007).

The NTA/Healthcare Commission Service Review in 2005/6 (Healthcare Commission/NTA, 2006) found significant inconsistencies in the implementation of one element of clinical governance in community prescribing services: clinical audit, which is regarded as a key indicator of commitment to quality. Twenty seven percent of community prescribing services had not undertaken any clinical audit in the previous 18 months.

Taken as a whole, the picture suggests only patchy or partial implementation of clinical governance at present.

2.6.3 Clarification of the differing roles and responsibilities of the wide range of organisations involved in clinical governance of drug misuse treatment is likely to be helpful in effective implementation

Drug treatment cuts across many organisational boundaries: health and social care, criminal justice, statutory and non-statutory. This means that clinical governance can be complex and there is wide variation in clinical governance delivery within the drug treatment sector.

- Providers of drug treatment:
- Mental health and foundation trusts provide much of the clinical drug treatment in some areas and have trust-wide clinical governance systems in place
- Primary care providers provide an increasing amount of community prescribing and should participate in clinical governance across the PCT
- The voluntary and private sectors mostly provide treatment commissioned by local commissioners but may also provide their services independently. They may have a variety of quality assurance mechanisms and will increasingly need to engage with NHS clinical governance systems.
- Primary care trusts act as bankers for the bulk of drug treatment funding on behalf of the local drug partnership and may also be the formal commissioners for local treatment provision. In the services they commission, they need to ensure clinical governance activity takes place and will need to resource services appropriately. They usually have lead responsibility for commissioned voluntary sector services, which do not themselves have statutory clinical governance obligations. They can work with others in the local drug treatment system to ensure that clinical governance systems are complementary and do not make excessive bureaucratic demands.
- Local drug partnerships take the lead on planning and commissioning treatment services in their area. They are well-placed also to take a lead in ensuring that effective local systems for clinical governance are in place and that clinical governance is embedded within the services they commission. However, the statutory responsibility for clinical governance will usually fall to some of their member organisations.

These and other responsibilities are described in more detail in chapter 5.

One particular factor causing variation has been a lack of recognition of who is responsible for clinical governance of any service they commission. For instance it is not uncommon for a local drug partnership to commission an independent service provider to provide a part of its drug treatment system. However, it may be the PCT that actually procures the service and contracts with the service provider, in which case the PCT is statutorily accountable for commissioning and monitoring clinical governance by the independent provider.

Some interventions provided for drug misusers – and the organisations providing them – are not covered by statutory requirements for clinical governance. These may include housing

and housing support, and some other interventions. They are often services provided by voluntary sector community and residential services. They may be local authority commissioned or provided services. Even where statutory requirements for clinical governance do not apply, it is important that all providers of all types of services to drug misusers strive for high quality care, and apply quality assurance and clinical governance principles outlined in this briefing. Increasingly, clinical governance will be expected of all commissioned services for drug misusers.

2.7 Frameworks and standards

A number of NHS clinical governance frameworks have been developed over the years. NHS bodies may already use one of these or a modified version and commissioners and providers will need to take this into account. However, they will also need to ensure that quality indicators or standards relevant to drug treatment are reflected in the clinical governance framework they adopt.

Appendix 3 describes a number of health, social care and other systems of quality criteria or standards for care, and the frameworks within which the core components of clinical governance are incorporated, including two of the best-known in healthcare services: the 'seven pillars' model, and the Department of Health Standards for Better Health. Standards for Better Health are mandatory standards for NHS healthcare. Mental health trusts and primary care trusts are (until new registration requirements take hold in 2010) assessed against the core Standards for Better Health by the Care Quality Commission and these can provide a suitable general framework of standards for all drug services against which the core components of clinical governance can be matched.

Recent key drug-specific standards include those arising from national clinical guidance and criteria developed for the NTA/Healthcare Commission Service Reviews. Drug treatment systems (and some services) have recently been assessed against these criteria, which also cover aspects within the domains of Standards for Better Health.

Clinical governance is the overarching framework and the related activities and processes for ensuring safety and for improving quality. Standards or agreed criteria of safety and quality, locally or nationally derived, are benchmarks against which provision can be measured, and by which the processes for achieving them can be evaluated.

Given the importance of Standards for Better Health (SfBH) and its comprehensive coverage of the core domains of clinical governance, those domains are used in this document for discussing in more detail the various components of clinical governance. Drug-specific elements arising from the SfBH domain are also discussed under the relevant sections.

The traditional 'Seven Pillar' model is described briefly in appendix 3 for reference. It describes the components of clinical governance in a slightly different configuration, which may be familiar to some.

2.8 Clinical governance and commissioning

The move in the NHS to World Class Commissioning – with its vision, competencies and assurance system for commissioning – is also relevant to the future place of clinical governance. Commissioning (including practice based commissioning) and clinical governance will need to be linked to ensure the health needs of the local population are met and services commissioned are compliant with SfBH.

Commissioners will need to commission services with clear and effective clinical governance in place and adequately resource appropriate clinical governance operation and development to assure this.

PCT commissioning and other NHS commissioning will itself benefit from the same clinical governance processes as provider organisations, including evidence-based practice, workforce competence, training, audit, information governance, cost effectiveness, lines of accountability and responsibility, etc. There is also considerable overlap between identified World Class Commissioning competencies (DH, 2007) and elements of clinical governance described in the next section. Commissioners will also want to consider how they performance monitor or manage clinical governance in the services they commission. This can be a challenge because much of effective clinical governance is about an enabling and learning culture and developing locally determined priorities for actions. However, some useful indicators might include:

- Patient experience – service user surveys, complaints, etc.
- Staff experience – evidence that time is made available for learning and reflection on practice, staff satisfaction surveys, staff report feeling able to 'blow the whistle' on misconduct or poor practice without fear of reprisal, etc.
- Completed audit cycles and critical incident reviews, and changes made that demonstrate what has been learned.

3 What clinical governance covers

3.1 Key points

- Clinical governance is constituted of a wide range of components that together contribute to safe and effective, high quality service provision
- The core domains of Standards for Better Health (SfBH) effectively cover all these components so are used in this document:
  - Safety
  - Clinical and cost effectiveness
  - Governance
  - Patient focus
  - Accessible and responsive care
  - Care environment and amenities
  - Public health.
- Each of these domains from SfBH has both a generic application in care delivery and specific applications in relation to drug treatment.

3.2 Introduction

The various components of clinical governance are usually described within an over-arching framework. The Standards for Better Health (SfBH) framework and the 'Seven Pillars' model for quality and clinical governance both encompass all the key components of clinical governance. SfBH domains are used below to categorise the components of clinical governance as many services will be considering their clinical governance activity within this context. The traditional 'Seven Pillars' model of clinical governance is described briefly in appendix 3 as it may be familiar to some readers.

All the SfBH domains are relevant to clinical governance in drug treatment services but some domains have more specific relevance and where this is the case these are explicitly described below.

The importance of effective, evidence-based clinical care – and how its safety and quality is assured – is also emphasised in the NHS Next Stage Review (DH, 2008) and is an important component of effective World Class Commissioning.

3.3 Safety

3.3.1 What it covers

The safety domain of SfBH covers issues such as deaths and other adverse incidents, child protection, medicines safety and hazardous waste disposal. These are all high profile issues for substance misuse services.

3.3.2 General benefits

Well developed clinical governance mechanisms can ensure that practices and treatments are safe for clients, staff and the public, reduce the possibility of untoward incidents, and engage staff in identifying areas for improvement without fear of a culture of blame.

3.3.3 Key aspects in relation to drug treatment

Proper risk management is vital in drug treatment and, in addition to the risks common to any workplace and public clinical environment, services need to pay special attention to:

- Safe prescribing and handling of medicines – appropriate prescribing, dispensing accuracy, on-site storage, home storage, prescription security and communication with pharmacists, etc.
- Risks to children from drug-misusing parents
- Blood-borne viruses – preventing and responding to needle-stick and other injuries, and vaccination of staff
- Staff safety, including lone working policies, safety away from base, etc.

Risk management includes both prevention and review of untoward incidents. Preventative processes include infection control, action on safety notices, safety and decontamination of medical devices, child protection procedures, medicines management and waste management. Review processes include incident reporting, investigation and review (including confidential inquiries into drug related deaths). It is an important principle of effective clinical governance that encouraging an appropriate culture of openness underpins the approach to dealing with untoward incidents. This is sometimes referred to as a 'fair blame' culture. While this does not remove or replace appropriate accountability for poor practice or negligence, it is an approach that anticipates that errors are inevitable in human practice and in organisations. It encourages maximum sharing of information, including concerning everyday errors, within a positive culture of learning, for the benefit of the patient, the worker and the system overall. It does not automatically equate individual errors with poor practice or sole responsibility of the individual. It is based on an understanding that more serious incidents are often due to accumulation of a series of smaller errors or actions. It encourages openness about untoward incidents and smaller errors as positive professional practice and is a powerful tool to avert future more serious incidents.

NHS and independent organisations providing services that may involve the management or use of controlled drugs are required by law to appoint an accountable officer. Accountable officers are responsible for ensuring compliance with misuse of drugs legislation and the safe, effective management of controlled drugs within their organisations and within those organisations with whom they contract relevant work.

NHS organisations (and independent organisation providing NHS services) need to meet specified risk management standards, set by the NHS Litigation Authority, in order to qualify for reduced contributions to its scheme for covering the costs of legal liabilities. Also see section 5.3.5.

3.4 Clinical and cost effectiveness

3.4.1 What it covers

The clinical and cost effectiveness domain of SfBH covers a wide range of issues associated with ensuring that treatments are individualised and evidence-based. It includes conformance to NICE technology appraisals and nationally agreed guidance, clinical supervision and leadership, continuing professional development, clinical audit and review, and cooperation between health and social care to ensure that clients' individual needs are met.

3.4.2 General benefits

Good clinical governance in this area is likely to increase assurance that clients achieve treatment benefits that meet their individual needs and that staff maintain relevant knowledge and skills and continue to develop reflective practice.

3.4.3 Key aspects in relation to drug treatment

All drug treatment services should be providing interventions in line with, or that properly take account of, the latest evidence-base, including any authoritative guidance on effectiveness. This will include taking account of evidence from high quality, peer-reviewed research and other emergent sources, NICE technology appraisals and clinical guidelines, Drug Misuse and Dependence: UK Guidelines on Clinical Management, and clinical guidelines for specific treatment locations, populations and professional groups, such as prisons, forensic physicians, etc.

Local clinical audit can monitor whether interventions are being delivered in accordance with guidance or locally determined standards and whether they are producing expected outcomes. The results of audit are used to action plan improvements. The NTA has published a guide to Auditing Drug Treatment (NTA, 2008a) against recent clinical guidance.

Local research and analysis on the impact of clinical interventions can also be useful. A range of measures can be used to compare the outcomes resulting from different treatments or the outcomes of different groups. The recently introduced Treatment Outcomes Profile (TOP) for monitoring progress of drug misusers can be incorporated into local audits, where appropriate.

Where published evidence of effectiveness of particular interventions is not available, clinical governance processes can help to ensure on-going evaluation of such practice, including the views of service users. This can help to assure both safety and effectiveness are being properly monitored either through focused work or through general systems of governance and exception reporting.

It is good practice for all, and a requirement for some, professional groups that staff are appropriately supported and supervised, including clinical supervision for clinical staff. Underpinning principles for supervision include the need for a supportive, open and non-threatening style that recognises the need for lifelong learning for all clinicians. There is more on clinical supervision at appendix 5.

Staff will normally need to participate in continuing professional and occupational development commensurate with their work, including mandatory training programmes (NB NHS mandatory training also applies to staff from the commissioned non-statutory sector). This will enhance competence of the workforce in the delivery of effective, and safe, treatment.

Team working is important in drug treatment, which involves working with clients with multiple needs, and therefore the requirements to involve multiple disciplines in their treatment. Team working applies both internally, e.g. senior management, clinical and multi-disciplinary teams, and externally, e.g. across organisational boundaries and sectoral frontiers (statutory/voluntary, health/social services, etc.).

3.5 Governance

3.5.1 What it covers

The governance domain of SfBH covers a wide range of issues of organisational governance, including the processes and culture to support staff to do their jobs openly and effectively; challenging discrimination and promoting equality; the appropriate recruitment and training of staff; and information, risk, performance and financial management.

3.5.2 General benefits

Attention to governance as part of clinical governance is likely to enhance managerial and clinical leadership and accountability, as well as the organisation's culture, systems and

working practices, to ensure that probity, quality assurance, quality improvement and client safety are central components of all the activities of the organisation.

3.5.3 Key aspects in relation to drug treatment

Staff competencies

Models of Care: Update 2006 (NTA, 2006b) includes an expectation that commissioners will ensure that local treatment systems have a range of medical competencies to meet the different needs of drug misusers. The doctors' roles and responsibilities consensus document (RCPsych and RCGP, 2005) clarifies the types and levels of drug treatment that different doctors (GP, psychiatrist, etc.) with different competencies can provide.

Services employing non-medical prescribers can refer to the NTA's good practice briefing on non-medical prescribing (NTA, 2007b) in order to understand the qualifications, competencies and accountabilities involved.

The competencies of all non-medical NHS staff, including drugs workers, should be matched to the NHS Knowledge and Skills Framework (NHS KSF) and to the Drug and Alcohol National Occupational Standards (DANOS), in addition to the requirements of each of their relevant professional bodies.

Competencies for non-NHS drug workers can be matched to the DANOS framework. Skills for Health is currently developing new qualifications specifically designed for those who work with drug and alcohol misusers. Skills for Justice provides a matching framework for staff in the criminal justice system.

NICE psychosocial guidelines (NICE, 2007c) and the 2007 Clinical Guidelines make recommendations for the content of keyworking, including psychosocial interventions, and for specific psychosocial interventions for common mental health problems and for drug misuse. Drug treatment services will need access to a range of relevant competencies, either within their services or through partnership arrangements with other providers. The competencies for staff providing psychosocial interventions are defined in Department of Health guidance for depression and anxiety (Roth and Pilling, 2007) and the NTA/BPS Psychosocial Interventions in Drug Misuse: a Framework and Toolkit for Implementing NICE-recommended Treatment Interventions (NTA & BPS, 2009).

Attention should also be paid to appraisal mechanisms. and recertification and revalidation for healthcare professionals.

Information management

The management of information in drug treatment is important because of the need to both protect and share information in the client's best interests.

It includes:

- Notekeeping and records management
- Confidentiality
- Consent
- Information sharing
- Information technology quality, connectivity, networking and security.

National, NHS and local rules on confidentiality and data protection are important to enable the effective and secure use of information. Information sharing protocols should be consistent with guidance from the local Caldicott Guardian.

For the drugs field, there is guidance on the management of NDTMS data, including Treatment Outcomes Profile data, at www.nta.nhs.uk/areas/ndtms and www.nta.nhs.uk/TOP.

The governance domain is also where the requirement for research governance sits. The SfBH standard requires that “Health care organisations which either lead or participate in research have systems in place to ensure that the principles and requirements of the research governance framework are consistently applied”.

3.6 Patient focus

3.6.1 What it covers

The patient focus domain of SfBH covers client dignity, consent for treatment and information sharing, complaints, dietary needs and service information. It also covers working in partnership with other organisations to ensure the client’s full range of needs is met and well-being ensured.

3.6.2 General benefits

Maintaining a patient focus ensures that treatment is provided in partnership with clients, their carers and relatives, respecting their diverse needs, preferences and choices, and in partnership with other organisations whose services impact on client well-being.

3.6.3 Key aspects in relation to drug treatment

Service users should be involved in the planning and delivery of their own treatment, and carers should also be involved where the client agrees, Carers may have their own needs and should be supported.

There is more on service users and carers in chapter 6.

Clear information sharing and confidentiality protocols, and their effective implementation, are also essential in the effective delivery of substance misuse treatment.

Partnership working with other organisations to meet a client’s full range of needs is critical to delivering effective support for recovery and reintegration for all clients. It is also vital for specific client groups, including:

- Young people
- Pregnant women
- Those with mental health problems, especially severe and enduring
- Those in prison or other parts of the criminal justice system
- Those with physical health problems requiring specialist treatment, including hepatitis and HIV.

3.7 Accessible and responsive care

3.7.1 What it covers

The accessible and responsive care domain of SfBH covers the involvement of clients and carers in designing, planning, delivering and improving services, and prompt and equitable access to services.

3.7.2 General benefits

Incorporating these approaches within the system of clinical governance locally is likely to promote a number of positive outcomes, including clients receiving services as promptly as possible, having choice in access to services and treatments, and not experiencing unnecessary delay at any stage of service delivery or of the care pathway.

3.7.3 Key aspects in relation to drug treatment

Local Involvement Networks (LINks)

"Local Involvement Networks (LINks) aim to give citizens a stronger voice in how their health and social care services are delivered. Run by local individuals and groups and independently supported - the role of LINks is to find out what people want, monitor local services and to use their powers to hold them to account. LINks will be established in most areas between April 2008 and September 2008. Each local authority (that provides social services) has been given funding and is under a legal duty to make contractual arrangements that enable LINk activities to take place."

www.dh.gov.uk/en/Managingyourorganisation/PatientAndPublicinvolvement/DH_076366

Service users and carers should be involved in the monitoring and development of service delivery, including the design and planning of local services. They might also be involved in, for example, interviewing for or training some staff or attending some operational or governance meetings.

All drug treatment services, and their commissioners, have a duty to ensure that services are accessible to their communities. They should take account of race, disability, gender, misuse of different drugs, etc in the planning, commissioning and delivery of their services.

Public authorities have statutory requirements under the Race Relations (Amendment) Act 2000, the Equality Act 2006 and the Disability Discrimination Act 2005. The NTA/Healthcare Commission Service Review in 2007/8 had diversity as one of its two themes and reported on good practice identified in the high scoring partnerships in Diversity: Learning From Good Practice In The Field (NTA, 2009).

Clients with health needs should be able to access care promptly and within agreed timescales. In drug treatment these timescales are represented by waiting times and the requirements to improve them to within specified limits.

3.8 Care environment and amenities

3.8.1 What it covers

The care environment and amenities domain of SfBH covers the safety, security, design, maintenance and cleanliness of services.

3.8.2 General benefits

Incorporating this within the system of clinical governance is likely to ensure that care is provided in environments that promote client and staff well-being and respect for clients' needs and preferences. Such environments and their amenities are more likely to support the effective and safe delivery of treatment, care or a specific function; provide as much privacy as possible; be well maintained and clean; and optimise outcomes for clients.

3.8.3 Key aspects in relation to drug treatment

For drug treatment services the emphasis is likely to be on:

- Aspects of client safety not covered by the SfBH safety domain, such as protection from violence and harassment
- Clients' privacy
- Protection for clients' children while on the premises.

3.9 Public health

3.9.1 What it covers

The public health domain of SfBH covers health improvement, disease prevention and incident/emergency management in collaboration with relevant organisations and communities.

3.9.2 General benefits

A focus of clinical governance on public health can promote, protect and improve the health of the broader population as well as the users of a particular service, and can reduce health inequalities between different population groups and areas.

3.9.3 Key aspects in relation to drug treatment

Drug treatment, and harm reduction measures in particular, can make a significant impact on public health. Particular issues to be covered in this domain include, for example:

- Harm reduction, including needle exchange, and interventions to reduce overdose and drug-related deaths
- Vaccination of staff and clients against blood-borne viruses
- Infection control, including hazardous waste management and decontamination of medical devices
- Smoking cessation interventions
- Action to tackle health inequalities by ensuring that disadvantaged groups can access drug treatment and other health interventions.

4 The components of clinical governance

4.1 Key points

- Clinical governance includes establishment of the lines of responsibility and accountability for care, quality improvement activities, policies that manage risk and procedures that identify and remedy poor performance.
- Some organisations and individuals have specific roles and responsibilities for elements of clinical governance but all organisations and all individuals have some responsibility to engage in clinical governance elements that improve client safety and treatment effectiveness.
- Clinical audit is a key quality improvement process driving and supporting clinical governance and is in need of improvement in many drug services.
- Policies should be aimed at managing a wide range of risks and should facilitate incident reporting.
- Procedures for identifying and remedying poor performance should avoid inappropriate blame and seek first prevent further negative impact on client care and then address individual and system causes.
- Clinical governance processes may usefully be timed to fit with other timetabled processes.
- Involving others outside drug treatment ensures proper clinical governance and provides access to additional useful resources and expertise.

4.2 Introduction

Clinical governance includes four key components:

- Clear lines of responsibility and accountability for the overall quality of clinical care
- A comprehensive programme of quality improvement activities – including clinical audit
- Clear policies aimed at managing risks
- Procedures for all professional groups to identify and remedy poor performance.

(Palmer, 2002)

Implementing clinical governance in drug misuse does not mean reinventing the wheel. NHS trusts and many voluntary sector providers will already have processes in place that can be adopted or adapted, or into which drug misuse-specific clinical governance can be fitted. There is already a wide range of data sources that will provide much of the information required to audit clinical practice.

Providers and commissioners may find it helpful to aim to integrate and streamline existing processes to fit with existing timetables for data collection, needs assessment, audit and performance management, etc.

4.3 Lines of responsibility and accountability

Responsibility and accountability are at the heart of clinical governance. The lines of responsibility and accountability within and beyond an organisation should be clearly defined and understood by all staff.

There is a range of individual and organisational responsibilities, including:

- Individual professional responsibilities, defined by a duty of care to patients, professional codes of conduct and registration requirements
- 'Duty of care' responsibilities of all caring organisations
- Chairs of boards' liability for health and safety, and equality schemes
- Employers' responsibilities to employees and vice versa.

These are then assured through accountabilities including:

- Healthcare professionals' individual accountability to their registering bodies
- Line management accountabilities
- Providers' accountability to commissioners
- Providers' and commissioners' accountability to:
  - Their boards
  - Registration and inspection bodies (principally the Care Quality Commission)
  - Their communities.
- Partnerships' accountability to NTA and regional stakeholders for annual treatment plans.

These and others should all be positioned in a comprehensive system of agreed accountabilities so that all staff in provider and commissioner organisations are clear who is responsible for what and accountable to whom. More on some of these specific roles and responsibilities is described in chapter 5.

A hepatitis nurse was seconded from an NHS trust to provide a vaccination service for clients at a local needle exchange service run at a multi-agency 'one stop shop'. The nurse discovered that the refrigerator used for storing vaccines had been unlocked and was being used to store food because the staff room fridge had broken. The nurse complained to the building manager that this was unsafe practice. After discussions with the service manager and commissioner, the contracts with the NHS trust and the one stop shop were changed to clarify that the nurse had overall responsibility for the safe storage of the vaccine and for the refrigerator, while the building manager was responsible for ensuring the refrigerator was maintained in good working order. The nurse subsequently developed a policy detailing the storage requirements and referencing the 'care and control of medicines' policy of the NHS trust, while the manager developed a policy for the building which included responsibility for checking the refrigerator for correct storage and temperature, and ensuring it was being used in accordance with the NHS trust requirements.

4.4 Quality improvement activities

A comprehensive programme of quality improvement activities includes:

- Clinical audit
- Continuing professional development
- Evidence based practice
- Research and development
- Effective monitoring of clinical care.

The key mechanism for quality improvement and the driver behind much clinical governance is clinical audit. This is covered both below and in more detail in appendix 4. The NTA has also separately published a framework for Auditing Drug Treatment (NTA, 2008a).

4.4.1 Clinical audit

Effective clinical governance commonly makes use of the clinical audit cycle. Topics to be addressed are usually decided at a local level with multidisciplinary agreement but may also be requested or required from outside the organisation carrying out the audit. Once a topic is agreed, typically:

- Criteria or standards are determined or agreed – these may relate to the process of care ('are we doing it right?') or the outcomes of care ('is it working?')
- Data is collected (or is provided from external sources) on how well the organisation is meeting the criteria
- The data is analysed to match performance against the agreed criteria or standards
- Any areas for improvement are identified
- Action is agreed with stakeholders.

Clinical audit can act as a driver for improvements in quality and safety because it provides evidence on the success (or otherwise) of interventions against agreed criteria and of changes needed. All clinical professional groups (doctors, nurses, pharmacists, psychologists, etc) can be expected to participate in clinical audit as part of their professional responsibilities for clinical governance.

Criteria or standards for audit come from various sources: both from nationally established sources (such as clinical guidance documents or inspection bodies) or may arise from statutory or contractual requirements, and can be generic or drug misuse-specific. Some current or recently established relevant external criteria are described in more detail in appendix 3.

Assurance of the match between standards and delivery is usually an internal process but it can also be an external one. Crucially, local provider multidisciplinary teams and their management groups will consider and respond to audits. Typically, in medium or large provider organisations, specific groups with remits for particular clinical areas report assurance to a clinical governance overview group. Occasionally, reporting may be to commissioning bodies or to national bodies, such as inspectorates. Communication of results must always flow back to teams and individuals involved, to allow discussion of findings and development or consideration of any recommendations so that improvements can be made.

For organisations within the NHS 'umbrella' much of this structure already exists in trusts, and the challenge for organisations is to support trust clinical governance leads and the whole staff group in ensuring clinical governance is a central element of delivery. However, organisations providing care entirely within the independent sector will need to establish their own reporting and assurance processes.

External assurance is described in the section on regulation and inspection in appendix 3.

A drug treatment service carried out a routine case note audit. The audit showed that 27% of case notes did not include reference to providing patients with advice about safe storage of medicines. Drug Misuse and Dependence: UK Guidelines on Clinical Management recommend that "patients must be made fully aware of the risk of their medication and of the importance of protecting children from accidental ingestion". The audit revealed that some keyworkers were using out-of-date record sheets and that administrative staff had not removed all the old-style record sheets from circulation or from the shared drive, which they then did. The audit was repeated three months later and compliance with recording this important information to patients had reached 95%.

4.4.2 Continuing professional development

Continuing professional development (CPD) is essential for a skilled workforce that can adapt to the changing needs of service users and to developments in treatment. However,

CPD can be demanding on resources so it should be focused on the most relevant areas by a process that involves:

- Identification of learning needs
- Drawing up a personal development plan (often as appraisal)
- Undertaking CPD in line with the personal development plan.

CPD may also be described in terms of a cycle of reflection, planning, action and evaluation.

A non-medical prescriber (NMP) assessed a client who had been referred to his service for help with his misuse of GHB (gammahydroxybutyrate). The NMP did not know anything about GHB and had to pass the client onto the doctor in the team. The NMP decided that this would be a good subject for his CPD. Firstly he asked himself what he needed to know and to be able to do (reflection). He wanted to know about GHB, what its effects were and how to treat its misuse. He then planned how he could learn (planning). He considered several options: he could ask his colleague who had taken on management of the patient; he could search on the internet for information (but would need to be able to differentiate evidence-based literature from unevidenced information); he could go to the medical library and ask the librarian for help with searching; and he could contact his network of non-medial prescribers in substance misuse to ask if any of them had experience of treating GHB misuse. He decided to do all of these things (action). He spoke to the doctor on the team who had experience of working with GHB clients. He read only peer-reviewed articles available on the internet, to ensure the validity of the information. The medical librarian was able to provide some anecdotal references but these were, in the main, descriptions of individual cases. Finally, he found a colleague on the NMP substance misuse network who had experience of detoxing a client from GHB on an in-patient unit and was able to provide lots of advice and information. He was then able to reflect on his learning (evaluation) and, together with the doctor, helped develop a care plan for the client. He then produced a presentation on what he had learned and presented it at the next team meeting.

4.4.3 Evidence-based practice

In order to ensure treatment is both ethical, and makes best use of resources, it should be based on the best available evidence of effectiveness. Evidence-based medicine has been defined as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients … integrating clinical expertise with the best available external clinical evidence from systematic research” (Sackett et al, 1996).

Evidence-based healthcare “….de-emphasises intuition, unsystematic clinical experience and pathophysiological rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research” (Evidence-Based Medicine Working Group, 1992).

The strength of research evidence depends on methods used, and applicability to the subject under question. Bodies with responsibility for evaluation of research (such as NICE, SIGN and the Cochrane collaboration) have drawn up hierarchies of evidence levels depending on research methodologies, design, and sample size.

The concept of evidence-based practice should not lead to a position in which proper professional judgement is replaced by simplistic application of guidance but it does require that appropriate weight is given to authoritative, evidence-based guidance or to alternative evidence from research or other appropriate sources. A judgement is also always needed as to the applicability of evidence in any particular case.

Key evidence-based guidance in drug treatment includes NICE drug misuse guidance and the 2007 Clinical Guidelines.

4.4.4 Research and development

Research should be set up within the auspices of the local research governance body, and the need for ethical approval should always be addressed. Principles of research governance are:

- The research should aim to answer a research question that has not yet been answered
- Design should be sufficiently robust and sample size adequate in order to draw a reliable conclusion
- Adequate resources to undertake research should be ensured in advance
- Plans for dissemination of findings should be in place prior to undertaking research.

A service user group was commissioned by the local drug partnership to carry out a survey of clients' views of the local NHS trust community drug team. The service user group enthusiastically developed a questionnaire and started to interview clients. The NHS trust learned about the survey and their clinical governance lead was concerned that it contained research questions rather than being just a survey or audit. The trust's audit and research department was asked to check the survey contents and confirmed that this was research and that approval by the local research and ethics group would be required. The commissioners were contacted by the clinical governance lead and arrangements made for an independent body to assist the service user group in developing a non-research survey and a protocol describing how the survey would be conducted.

4.4.5 Effective monitoring of clinical care

High quality systems for clinical record keeping and the collection of relevant information are essential components of the effective delivery of high quality care, both for the management of a particular individual and for the overall quality of care delivery.

There are established professional and contractual standards for clinical record-keeping and for contributing to appropriate recording of key data in healthcare organisations, which in substance misuse may involve local initiatives, such as recording vaccination programmes, and national reporting of key data required by commissioners, such as NDTMS data. Such data can contribute to effective monitoring of components of clinical care and to overall delivery.

4.5 Policies aimed at managing risks

As with poor performance (see section 4.6), risk management is as much about organisational culture as anything. An organisation and staff open to and welcoming of critique, and willing to learn from mistakes, is more likely to reduce risks and prevent the recurrence of mistakes. However, this culture should also be supported by policies that clearly outline how risk is managed in various areas. These should cover both proactive and reactive management: seeking to prevent incidents and responding effectively if near misses or actual incidents do occur.

Critical policies for managing risks in drug treatment include:

- Child protection
- Safe prescribing and handling of medicines
- Blood-borne viruses – preventing and responding to needle-stick and other injuries, and vaccination of staff
- Staff safety, including lone working policies, safety away from base, etc.

Policies should cover how the organisation will:

- Ensure a range of mechanisms that make reporting by staff and patients easy and safe
- Investigate reports and incidents, including near-misses
- Act on risks identified and feedback to staff.

It is also vital to train staff to identify situations when a patient safety incident is more likely to occur and make it easy for them to report when patients have, or could have, been harmed (NPSA & NHS Confederation, 2008). The National Patient Safety Agency (NPSA) has produced a Foresight Training Resource Pack to improve the safety of patients treated in the NHS (NPSA, 2008).

Drug service staff at their weekly team meeting identified an increasing number of unresolved risks for staff who had to work at many different sites for different clinics. These included the need to carry heavy case notes to satellite clinics, and leaking urine samples. The manager of the service ensured the staff concerns were minuted and, with the team's help, categorised the concerns into those needing immediate attention and those where a longer term solution would be acceptable. For each problem, staff were invited to offer solutions and the manager developed action plans to either remove the risk or reduce it to an acceptable level. The action plans were monitored by the drug service's clinical governance group, which also provided additional support. Risks that could not be resolved through the action plan were escalated via the clinical governance group to the employing organisation's clinical and non-clinical risk groups and the items added to the organisation's risk register. The manager ensured that any incidents or near-misses were recorded on the service's incident reporting forms so that these were all logged. The action plan and risk register continue to be monitored routinely and weekly team meetings report progress with the action plans. Weekly team meetings now always include health and safety as a standing agenda item to ensure that staff raise issues of concern at the earliest opportunity rather than waiting for problems to mount up and get out of control. New risks identified are added to the risk register together with an action plan.

4.6 Procedures for identifying and remedying poor performance

Poor performance may be at an organisation or individual level but, even if organisational, it will involve individuals delivering an unacceptable standard of care and this will need to be tackled. However, it is also important to avoid a culture of inappropriate blame: poor performance should usually be seen as a failure in one or more systems and as an opportunity for learning and improving. Simply blaming one or more individuals and taking them out of the system will not prevent future poor performance if there is an unresolved shortcoming in the system.

The mechanisms for identifying and remedying poor performance can and should usually be split as follows:

4.6.1 Identifying poor performance

Poor performance may be identified by:

- Investigating the causes of serious untoward incidents and near misses
- A whistle-blowing policy that allows colleagues to report poor performance
- Client complaints, whether informal or formal
- Effective supervision and appraisal against specified standards of performance
- Audit or inspection findings.

4.6.2 Remedying poor performance

Depending on the seriousness of the poor performance, its impact on client safety and whether and how previous efforts have failed, remedying individual poor performance may involve an escalating scale of actions at different levels. This may start with the line manager, move up through the employing and commissioning organisations, and may even involve a professional registration body or the National Clinical Assessment Service (NCAS).

Any actions should aim to:

- First neutralise the situation, preventing any further poor performance from impacting on client care. This may require more active support for care delivery or an individual's temporary suspension from a particular practice or from employment by the employer, or suspension from the right to practice by a registration body
- Next, investigate the nature and causes of the poor performance
- Then rectify the poor performance by addressing training needs, personal problems, inappropriate policies and procedures, etc as appropriate
- And, finally, when satisfied that individuals concerned are able to perform to the required standard and that any system issues have been resolved, restart if possible.

A nurse reported to her line manager that Dr Z was prescribing unusually low doses of a particular medicine. Under-performance procedures were instigated and the matter was investigated with the involvement of Dr Z's supervising consultant. Dr Z continued to practice but patients on the medicine concerned saw an alternative prescriber for review. Investigation determined that Dr Z was in need of education on the latest evidence with regard to appropriate dosing and that the trust's prescribing policy was also out of date. After training and revision to the policy, Dr Z was able to recommence prescribing the medicine concerned, with enhanced supervision arrangements that Dr Z was happy to receive.

4.7 Timing of clinical governance processes

Some externally-driven processes – including annual treatment planning and clinical audit across an organisation – may require drug needs assessment and audit to be conducted at particular times of the year. Their results can provide useful information back to the organisation that helps determine where change is needed. It can be helpful to time internal clinical governance processes and the clinical audit cycle to fit in with these other timetables to minimise unnecessary duplication or repetition.

4.8 Involving others

Large organisations (PCTs, mental health trusts and large voluntary sector providers) may have a range of internal bodies and committees providing expertise and oversight on particular subjects in the clinical governance framework, such as health and safety, prescribing and infection control. Smaller organisations may cover all of these subjects through simple internal mechanisms. Alternatively, commissioners might commission the involvement of the external bodies as a resource to smaller providers or require them to be involved in the clinical governance processes of smaller providers through contractual arrangements. Practical examples might include:

- Medicines control – a PCT's pharmacy advisor provides advice, model protocols, patient group directions, etc. to commissioned providers around appropriate prescribing, supervised consumption, storage, enhanced services and liaison with community pharmacies, etc.

- Infection control – the mental health trust's infection control nurse includes PCT-commissioned and other local providers in their annual examinations of infection control procedures.

At a more strategic level, the director of public health might provide leadership and support around, for example, infection control and harm reduction measures.

5 Roles, responsibilities and assurance in clinical governance

5.1 Key points

- Everyone involved in commissioning, providing and using drug treatment has a part to play in clinical governance
- Statutory obligations for clinical governance are different for different provider types, but all providers can benefit from a strong focus on clinical governance
- Large providers can usually be expected to have their own organisation-wide clinical governance frameworks
- Smaller providers may adopt substantially less extensive clinical governance assurance systems but may be able to adapt or integrate key elements of the systems used by larger organisations (e.g. for reporting and responding to critical incidents, undertaking clinical audit or incorporating up-to-date guidance)
- Drug treatment commissioned as part of the Drug Interventions Programme will fall within the normal clinical governance arrangements for local drug partnership-commissioned treatment but other, non-clinical, interventions provided through the criminal justice system (such as groupwork programmes delivered by the probation service and some prison-based programmes) may fall outside these arrangements. They may benefit from clinical quality assurance arrangements and from being brought under the clinical governance 'umbrella'
- PCTs' clinical governance duties and responsibilities for the services they commission are increasingly clear and may drive improvements across the range of service providers
- Local drug partnerships can play a role in providing strategic support for clinical governance systems across all drug treatment providers and in particular for the intra-organisational interfaces
- PCTs can incorporate the development of clinical governance systems into their service level agreements with commissioned non-statutory services and their statutory providers.

5.2 Introduction

This section describes the roles and responsibilities of organisations, groups and staff in clinical governance. It attempts to draw some distinction between the obligatory accountabilities described in section 4.3 and the broader roles and responsibilities that can help clinical governance to be effective and useful.

5.3 Organisations

A wide range of organisations and groups (and their personnel) have roles and responsibilities in relation to clinical governance. This section details the different roles and responsibilities of:

- Providers
- Commissioners
- Employers
- Clinical governance quality or audit groups
- Organisations with regional and national oversight.

As this list suggests, some organisations will have multiple responsibilities or play multiple roles. For example, a PCT may both commission and provide services; it will also be an employer and will be a key partner in local clinical governance groups.

A summary of the principal roles and responsibilities across the drug treatment and broader health and social care systems is provided in figure 2 on page 43?.

Where relevant, links to examples of local practice in appendix 1 are given.

5.3.1 Providers' responsibilities

General

All providers can be expected to:

- Designate a named clinical governance lead in every service
- Operate in accordance with and participate in the clinical governance activity of their parent or commissioning body.

All drug treatment service providers will be assessed against various Care Quality Commission criteria. In addition to criteria for all providers, there are specific requirements for specific providers, described below. Many clinical staff (doctors, nurses, clinical psychologists and pharmacists) have a professional duty to participate in clinical governance under the terms of their professional body registration and regardless of the type of service in which they are based.

Mental health and foundation trust drug treatment services (local practice example 9.2)

NHS healthcare services have previously been assessed against the Standards for Better Health by the Healthcare Commission and this will be continued by the Care Quality Commission in 2009-10. New arrangements are expected from 2010.

Mental health and foundation trust substance misuse services are required to operate in accordance with, and actively participate in, their trusts' clinical governance processes.

Primary care based drug treatment services

Like mental health trusts, primary care based services have previously been assessed against the Standards for Better Health by the Healthcare Commission and will be subject to new arrangements from 2010.

Primary care drug services can be delivered according to a variety of models but, whether operating as independent contractors or as PCT-contracted or PCT-run services, they share common responsibilities for clinical governance and will be required to participate in clinical governance activity across the PCT.

Non-statutory drug treatment services (local practice examples 9.1 and 9.3)

The requirements for non-statutory service providers can be complex because of their disparate nature, the wide variety of services they provide and the different ways in which they are commissioned. Services commissioned by PCTs are likely to be accountable to the commissioner for clinical governance, and assured against the Standards for Better Health (or future standards). Non-statutory services may additionally become answerable to commissioners outside healthcare organisations, funding bodies and, in the case of seconded NHS staff, NHS trusts. All will therefore benefit from a strong focus on clinical governance within their own organisation.

Other specific requirements include:

- Independent healthcare providers will usually be required to register with the Care Quality Commission, as governed by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009

- Residential rehabilitation services that meet the definition of accommodation for persons who require treatment for substance misuse will be required to register with the Care Quality Commission, as governed by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009
- Residential rehabilitation services that provide detoxification and other healthcare may be required to meet additional healthcare standards
- Services that are not PCT-commissioned and not currently required to register with the Care Quality Commission but that do provide treatment (e.g. individual psychosocial therapies or group work) may be contractually required to carry out assurance against other standards by funding bodies, for instance against Best Value Performance Indicators as defined by the relevant Local Authority. An additional form of assurance might also be considered, such as an accreditation scheme, for example, that provided by the European Association for the Treatment of Addiction (EATA).
- Services funded through Supporting People will be regularly reviewed by local Supporting People teams to ensure they meet standards laid down by central government.

How these different requirements translate into the clinical governance expectations on examples of different types of non-statutory providers with different configurations of services is shown in table 2.

Large providers can usually be expected to have their own organisation-wide clinical governance frameworks, with responsibility for clinical governance resting at board level. Smaller providers may adopt substantially less extensive clinical governance assurance systems but may be able to adapt or integrate key elements of those systems used by larger organisations (e.g. for reporting and responding to critical incidents, undertaking clinical audit or incorporating up-to-date guidance).

Where an independent provider organisation's services are spread across a wide geographical area and encompass a number of different treatment modalities, frequent meetings of all service governance leads may not be feasible, and much of the discussion and analysis may take place at board level.

Where a provider has multiple purchasers or commissioners, it may be unavoidably required to engage in multiple clinical governance systems. Commissioners can minimise the demands arising from these requirements by specifying the need for clinical governance and appropriate standards, and performance managing this rather than how it is delivered.

Service example	Clinical governance approaches (in addition to general attention to all the elements of clinical governance listed in table 1)
A service providing Tier 2 interventions but with no needle exchange	• If commissioned by PCT, requirements for clinical governance including involvement in local processes and adherence to SfBH (or their replacement) • Particular attention to: - Competencies of staff delivering psychosocial interventions.
A service providing Tier 2 interventions including needle exchange	• As above, plus: • Particular attention to: - Risk management - Competencies of staff delivering harm reduction interventions - Supervision of clinical staff (e.g. nurses) - Infection control.
A service delivering Tier 3 interventions	• If PCT-commissioned, PCT requirements for clinical governance including designated clinical governance lead, involvement in local processes and adherence to SfBH (or their replacement) • Particular attention to: - Competencies of clinical staff, training, CPD, supervision, etc - Clinical effectiveness of treatments - Safe handling of medicines.
A structured day programme providing psychosocial interventions	• If commissioned by PCT, requirements for clinical governance including involvement in local processes and adherence to SfBH (or their replacement) • Particular attention to: - Competencies of staff delivering psychosocial interventions.
A residential service registered as a care home with nursing and providing detoxification	• CSCI and new CQC requirements: - Adherence to National Minimum Standards for Care Homes for Adults (18–65) and, if taking clients under the age of 18, Supplementary Standards for Care Homes Accommodating Young People Aged 16 and 17 - Plus higher and additional standards for facilities and equipment - New registration requirements from 2010. • PCT requirements if commissioned for detoxification • Particular attention to: - Competencies of clinical staff, training, CPD, supervision, etc - Clinical effectiveness of treatments - Safety of medicines.
A residential service not registered as a care home and not providing detoxification	• If Supporting People-funded, will be required to meet standards laid down by central government and will be regularly reviewed by local Supporting People teams • Clinical governance may be required and performance managed through a contract.

Table 2. Examples of clinical governance approaches for different types of non-statutory sector drug treatment services

Prison-based drug treatment

Providers of prison drug treatment are accountable for continuously improving quality of services and standards of care. All members of treatment teams, both clinical and psychosocial, have a role in clinical governance procedures and in decision making about improvements. As a minimum teams need to decide who is to lead on clinical governance (usually a doctor, nurse or manager), agree plans for documenting and reporting incidents, and choose priorities for improvement.

Prison healthcare commissioned jointly by the PCT and prison – including drug treatment programmes – will be subject to the same clinical governance requirements as other healthcare for NHS patients. Drug treatment that is directly commissioned by the prison service or private prisons – including CARATs, accredited cognitive behavioural programmes and therapeutic community programmes – will fall outside these requirements. It will still be important to ensure that clinical governance mechanisms are in place here.

Prison healthcare managers are responsible for the coordination of all healthcare interventions delivered within the prison and will want to ensure that clinical governance arrangements are in place. In publicly-funded prisons they are accountable to the primary care trust and their employing authority. In contracted prisons they are accountable to the director of the prison or, if healthcare is contracted out to a third party organisation, jointly accountable to the clinical director of that organisation and to the director of the prison.

NOMS Interventions and Substance Misuse Group and governors (or directors of contracted-out prisons), as appropriate, will also want to ensure quality and safety by ensuring that effective clinical governance is in place for all programmes.

NB The Prison Drug Treatment Strategy Review now underway could result in significant changes to the funding, commissioning and delivery of prison based drug treatment, and the continuity of care of drug-using offenders on release, in which case the exact details of clinical governance arrangements and responsibilities might also be affected.

Community criminal justice drug treatment

Criminal Justice Integrated Teams (CJITs) are commissioned by local drug partnerships and delivered by a range of voluntary and statutory providers. NHS providers will usually already have clinical governance arrangements through their parent body but it may enhance quality if commissioners can ensure that clinical governance arrangements are in place in all providers.

Drug treatment for drug misusing offenders who are subject to community orders with a Drug Rehabilitation Requirement will usually be delivered by services commissioned by PCTs to provide treatment to other drug misusers and will therefore be subject to the same requirements as other healthcare for NHS patients. However, psychosocial interventions, such as cognitive-behavioural programmes like ASRO and OSAP, are commissioned or provided by the probation services and fall outside these requirements, although they are accredited by the Correctional Services Accreditation Panel against criteria that cover some of the elements of clinical governance. It may enhance quality if commissioners can ensure that clinical governance mechanisms are in place here.

Medical staff (primarily forensic physicians but also forensic nurses) contracted by police authorities to provide generic primary care services in custody environments will often be called to assess or treat drug misusers in custody. Although they are not commissioned to provide specific drug treatment services through local drug partnerships it may be helpful to consider involving a representative forensic physician on a local clinical governance group.

5.3.2 Commissioners' responsibilities

There is a difference between lines of accountability for how drug services are commissioned and managed in many areas, and for clinical governance. Although drug partnerships and their commissioners are commonly the driving force behind commissioning, it is usually the PCT which provides the legal and financial mechanisms through which commissioned services are contractually bound. Therefore the PCT has the statutory responsibility to ensure proper clinical governance in commissioned services. This statutory responsibility should not, however, detract from the importance of the drug partnership and its commissioners playing a lead role in supporting clinical governance mechanisms across the partnership's providers.

Practical action to support clinical governance that commissioners may usefully develop includes:

- Recognising the resource implications of clinical governance through appropriate resource allocation. Commissioners need to recognise their role in supporting training, supervision, appraisal and accreditation of staff, staff time to implement the assurance process for clinical governance, and resources for IT, clinical audit and data analysis, and research and administration.
- Ensuring contracts and service level agreements with providers explicitly specify the need for robust clinical governance structures and processes, and how compliance should be evidenced, including requirements to appoint a clinical governance lead and to participate in appropriate clinical governance group(s).
- Putting in place robust mechanisms to monitor clinical governance implementation.

With such assurance mechanisms in place, commissioners may minimise pressures for direct involvement in day-to-day management of how providers deliver their services.

Local drug partnerships (local practice example 9.4)

As bodies with a vital role (and often taking the lead) in the commissioning process, local drug partnerships are ideally placed to ensure a clinical governance framework is commissioned and supported in all services providing treatment for drug misuse in their area. Any such clinical governance requirements would need to be reflected in service level agreements. Contract managers could take a role in overseeing the whole treatment system and in particular the intra-organisational interfaces by bringing together all commissioned (and even non-commissioned) service providers to share clinical governance learning and develop interagency referral and care pathways. A partnership-wide clinical governance lead may be useful, especially in the early stages of setting up broader sharing from clinical governance across providers. However, partnerships and leads should take care not to risk compromising clinical governance systems that are already established and working well within the core provider organisations.

Partnership members, including PCTs and local authorities, may also have specific responsibilities, described below.

Primary care trusts (local practice example 9.1)

Services provided directly by trusts are likely to be automatically included in the trust's clinical governance process. However, primary care trusts need to ensure that services provided indirectly, i.e. commissioned by or on behalf of the primary care trust, are given clear contractual requirements to undertake clinical governance and that they ensure compliance with quality standards. There is some evidence to suggest that this expectation has not always been acted upon. A pilot programme on implementation of clinical

governance in PCTs found that: “A significant number of PCTs had failed, hitherto, to recognise that their clinical governance duties and responsibilities extend to those services that they commission, as well as services they provide” (Modernisation Agency, 2004).

Clinical governance leads in PCTs need to ensure that they support commissioned non-statutory sector drug treatment services to implement appropriate clinical governance processes and that structures exist to assure such clinical governance to the primary care trust’s clinical governance overview committee.

It is important to note PCTs’ responsibilities to provide prison healthcare services. All prison healthcare services routinely treat inmates for drug problems. PCT commissioners may have additional challenges in commissioning and supporting clinical governance for treatment to prisoners but exactly the same principles apply as for other providers commissioned by the PCT.

Local authorities

Generally local authorities will commission within a partnership framework, but occasionally they may not have this support. It is good practice that local authorities ensure a contractual obligation for clinical governance from service providers. Local authorities will set Best Value Performance Indicators relevant to the services they commission and the outcomes they want to see.

Residential rehabilitation placements are usually at least partially Community Care-funded and may increasingly be the subject of regional or other commissioning arrangements. Commissioners and Community Care managers should consider how clinical governance arrangements are assured in services that will often be outside the partnership area.

Prisons

Primary care trusts are responsible for the commissioning of healthcare services within publicly funded prisons in England and should therefore ensure proper clinical governance as for other healthcare for NHS patients.

In contracted prisons, managers of healthcare services provided by the contractors themselves are accountable to the director of the prison. Where a clinical service is contracted out to a third party organisation, the healthcare manager is jointly accountable to the clinical director of that organisation and to the director of the prison. The quality and safety of these healthcare services will be better ensured if the director of the prison or the clinical director or both ensure proper clinical governance is in place.

Some drug treatments (including CARATs, accredited cognitive behavioural programmes and therapeutic community programmes), are directly commissioned and contract-managed by the prison service. It may be beneficial if governors and directors ensure that these psychosocial contributions to the overall treatment care plan are included in clinical audit and improvement processes.

NOMS Interventions and Substance Misuse Group is responsible for coordinating the delivery of non-clinical drug treatment programmes in prisons, including CARAT services, and could ensure proper clinical governance is in place.

NB The Prison Drug Treatment Strategy Review now underway could result in significant changes to the funding, commissioning and delivery of prison based drug treatment, and the continuity of care of drug-using offenders on release, in which case the exact details of clinical governance arrangements and responsibilities might also be affected.

Community criminal justice treatment

Community drug treatment interventions for offenders (whether provided via the Drug Interventions Programme or, for example, via community orders with Drug Rehabilitation Requirements) are all commissioned through local drug partnerships and so should be subject to the same clinical governance arrangements as mainstream drug treatment. Local

probation managers and Regional Offender Managers may be able to play a proactive role in the joint commissioning process and can help to ensure clinical governance arrangements are in place.

Police

Police authorities employing forensic physicians and forensic nurses to provide generic primary care services in custody environments will want to support these individuals to meet their professional responsibilities for clinical governance. Police involvement in local drug partnerships may provide an opportunity to ensure that drug treatment provided in custody is represented in local clinical governance mechanisms.

5.3.3 Employers

Mental health, foundation and primary care trusts' accountability for clinical governance can extend to trust employees on secondment, with trusts being accountable for assuring the quality of the places of work of their employees.

5.3.4 Clinical governance interface – clinical governance quality or audit groups

Healthcare trusts, and some non-statutory services, have clinical governance groups or departments, with nominated leads for key areas and an overall lead. Governance structures generally comprise several committees for various aspects of governance, such as prescribing, psychological therapies, treatment effectiveness, risk management and so on reporting to a clinical governance overview committee.

It is good practice for healthcare provider trust clinical governance leads to liaise with the clinical governance leads, clinical leads and service managers of the drug services which the trust provides or is responsible for, to assure incorporation into overall trust clinical governance processes to support and assure safe and effective care. Trust clinical governance departments can provide practical support to drug services, for instance by:

- Enabling them to devise standards frameworks specific to drug misuse
- Providing policy frameworks, for example for risk management, analysis of serious untoward incidents, descriptions of care pathways and any other relevant clinical guidelines, etc.
- Facilitating clinical audit, by providing training, expertise and devising data collection tools. Data analysis may also be provided by trusts if they are also the provider.

Some clinical governance oversight and/or coordination across the drug treatment system is likely to be important in all drug partnership areas in supporting delivering an effective overall system of high quality care. This is because service users will often use a number of the statutory and non-statutory health and social care providers within a partnership area and because it will give providers an opportunity to share knowledge and skills in delivering effective clinical governance. This co-ordination of clinical governance could also allow more effective provider input to the annual treatment planning process. Unless there are already suitable mechanisms, a partnership-wide clinical governance committee/subcommittee may be a good mechanism to address this issue most effectively. This may be a role for a current partnership-wide drug reference group, or a reinvigorated or reconstituted shared care monitoring group, or other suitable local group. However it is constituted, it is likely to be vital that such a group includes adequate representation from non-statutory providers as well as statutory clinical services. The full membership of the group might be determined by reference to the various treatment pathways followed by service users so – in addition to specialist providers – might include, for example, representatives of GPs, forensic physicians, prisons, probation, local authority, etc. Such a group might also formally feed back progress and plans to the drug partnership as well as support clinical governance priorities of the services.

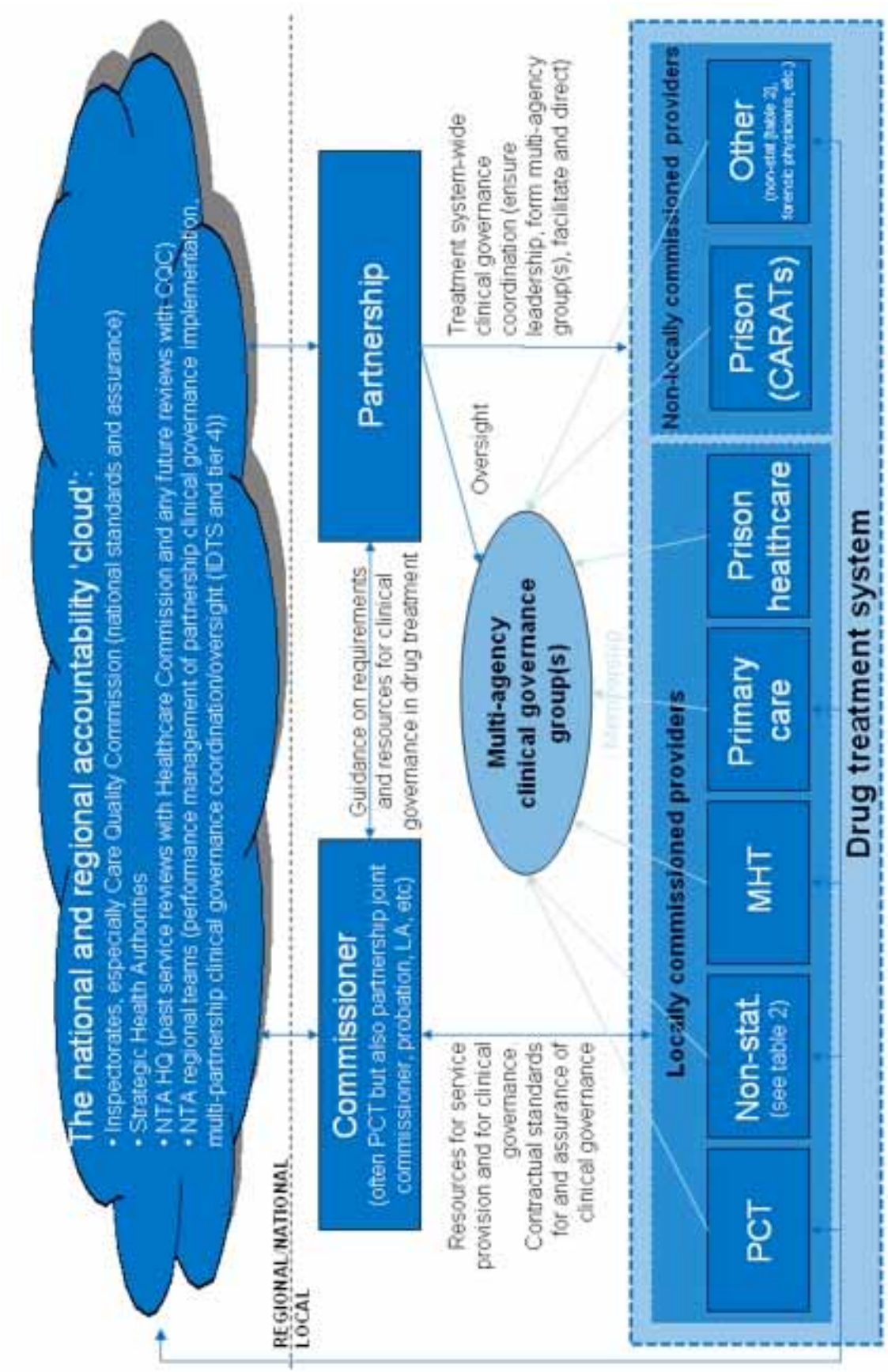
Drug partnerships can take a lead role in strategic support for clinical governance across the whole treatment system and in bringing together these partnership-wide clinical governance committees/subcommittees.

5.3.5 Organisations with regional or national oversight

A range of regional and national organisations have a role in clinical governance:

- Strategic health authorities (SHAs) may have their own clinical governance leads and will aim to fulfil a strategic responsibility for clinical governance at the interface of the strategic health authority and its constituent trusts. They will assist trusts in the development and review of their clinical governance strategies, and ensure that strategies across the SHA are compatible. They support and monitor clinical governance across the SHA, including advising and supporting trusts in the management of serious untoward incidents, issues of poor clinical performance and to promote patient safety (CGST, 2005).
- NTA regional teams include requirements for clinical governance in annual treatment planning and in performance management
- The Care Quality Commission will set and monitor registration requirements for a range of health and social care services
- The NHS Litigation Authority, which provides a contributory scheme for covering the costs of legal liabilities in the NHS, has standards for risks management. Compliance with these can reduce the cost of scheme contributions. There are risk management standards for mental health and learning disability trusts (including in relation to dual diagnosis), for PCTs, and for private sector providers of NHS care through Independent Sector Treatment Centres and as part of the Extended Choice Network.
- The National Patient Safety Agency (NPSA) has a remit to learn from patient safety incidents in the NHS through the mandatory National Reporting and Learning System (NRLS) for adverse healthcare events and ‘near misses’ in the NHS. The NPSA also ensures research is carried out safely, through its responsibility for the National Research Ethics Service. And its National Clinical Assessment Service (NCAS) provides confidential services to help manage concerns with the performance of NHS practitioners.

Figure 2: Principal organisational roles and responsibilities in clinical governance



5.4 All staff

'Clinical governance is everyone's business' NHS Clinical Governance Support Team

Clinical governance affects people as individual staff and within teams at all tiers of health and social care – this section sets out the different parts people play and the roles and responsibilities they have at each level for ensuring and improving quality in services.

NB Many clinical staff (doctors, nurses, clinical psychologists and pharmacists) have a professional duty to undertake clinical governance under the terms of their professional body registration and regardless of they type of service in which they are based.

5.4.1 Individual staff

Individuals' roles and responsibilities for clinical governance are discharged through doing the best job they can in the light of service user and public interest, for example:

Clinical leads and managers

- Champion clinical governance and can provide motivation and direction
- Implement and standardise safe and effective practice through service guidelines and protocols
- Enable training, supervision, and appraisals as appropriate for whole team
- Set up and lead clinical audit teams to run clinical audits
- Set up and lead clinical governance teams to run clinical governance processes
- Make clinical governance reports against standards frameworks.

Clinical staff

All staff delivering treatment interventions have a general responsibility to engage in clinical governance. Staff with professional clinical responsibilities, such as doctors, nurses, clinical psychologists and pharmacists, have mandatory registration with their professional bodies. Through these they must adhere to particular professional codes which require them to engage in key clinical governance activities that help to promote and maintain high quality clinical care. These include requirements to:

- Adhere to good practice guidelines and protocols
- Maintain skills and knowledge through continuing professional development
- Report serious untoward incidents (SUIs) and participate in SUI reviews
- Participate in clinical audit.

Some staff may be voluntarily registered with a professional organisation – such as the Federation of Drug and Alcohol Professionals (FDAP) – that requires them to adhere to codes of conduct for safe and effective practice.

Reception and administration staff

- Maintain data quality and ensure data collection
- Ensure clear and timely communication
- Enable service user access to information, and treatment
- Facilitate service user feedback and complaints.

Cleaners and caretakers

- Adhere to protocols regarding infection risk, and health and safety
- Maintain a safe and secure environment.

5.4.2 Teams

Collaborative and open team-working is essential for good clinical practice, and this is especially important for management of drug misuse where multidisciplinary team working is the cornerstone of effective treatment, and is usually multi-agency. Teams that deliver high quality care:

- Ensure that the interests of service users are always the focus of their actions
- Understand each others' roles and responsibilities and ensure appropriate designation of tasks
- Share information and knowledge on a 'need-to-know' basis where this is in the interests of the service user
- Support each other to deliver the best possible care
- Monitor and audit their practice and are not afraid to challenge poor practice, without blaming individuals
- Work together to learn lessons, and change practice to improve the quality of service.

6 Service users and carers

Service users and carers have a number of vital roles in clinical governance. There are effectively three aspects to service user involvement in clinical governance:

1. Patient focus (section 3.6):
   - Being treated well in treatment
   - Being involved in the planning and delivery of their own treatment.
2. Accessible and responsive care (section 3.7) - being involved in the monitoring, development, design and planning of local services.
3. As service providers themselves, including peer support and advocacy.

Rights and responsibilities

Roles in 1 and 2 are often combined and expressed in the rights of service users, but service users also have responsibilities, including observing service rules and keeping to the terms of their care or treatment plan (e.g. keeping appointment times, having drug tests and observing medication regimens). These responsibilities cannot be directly controlled and performance managed by the service in the way that rights can but paying attention to patient focus and providing accessible and responsive care may help service users meet their responsibilities.

It is good practice for carers to be involved in the planning and delivery of an individual's treatment, where the service user agrees, and in the design and planning of services more generally. Carers may also have needs of their own that need to be recognised, assessed and supported, in which case they may effectively become service users themselves and be involved in all the aspects of clinical governance above.

These elements of patient-centred care are a priority of High Quality for All (DH, 2008), which emphasises the needs "to organise care around the individual, meeting their needs not just clinically, but also in terms of dignity and respect" and to "give patients more rights and control over their own health and care".

In practical terms, it is good practice for drug treatment service providers and commissioners to ensure that attention is paid to:

- Feedback mechanisms from service users and carers to services
- Strategic planning for improved service delivery
- Service user and carer support, advocacy and peer-led training
- Service user and carer volunteer policies
- Service user and carer rights and responsibilities
- Service user and carer involvement in recruitment
- Service user and carer payments for involvement in monitoring, development, design and planning of local services.

Service users and carers may need to be educated, trained and supported to become involved in these roles. For example, they need to understand drug treatment and treatment options if they are to be involved in planning their own care. And to be effectively involved in the planning of service delivery they may need training and support, especially in the

language and processes of organisational and committee work of which they may have no previous experience.

Some service user and carer organisations may be commissioned to provide clinical services, in which case all the roles and responsibilities described in section 5.3.1 and 5.3.3 will become applicable to them. However, commissioners may need to make extra efforts to ensure that staff in these organisations are trained and supported to undertake clinical governance.

Some service users may be involved in a combination of these aspects: perhaps as a service user still, as a user involvement lead and as a provider of services to others. These multiple roles may be difficult for them to manage and they may need additional support.

Additional information on service user and carer involvement is contained in the NTA publications, NTA Guidance for Local Partnerships on User and Carer Involvement (2006c) and Supporting and Involving Carers (NTA, 2008b).

7 Making clinical governance happen

7.1 General

Clinical governance is a multi-faceted framework and its full implementation in any organisation involved in commissioning or providing drug misuse treatment can be a complex process and may take time.

Organisations with little or no clinical governance in place should make a start. Other organisations can use this document to consider how to improve further. It can be relatively simple to get the basics right and then progressively to build more effective systems.

Where can you start?

- Providers – appoint a clinical governance lead if not already in place
- Partnerships – consider the need for a partnership-wide lead
- Providers, commissioners or partnerships – clarify responsibilities for clinical governance
- Providers – audit existing clinical governance practice and consider the priorities for safety and quality assurance
- Providers and commissioners – establish priority local clinical governance mechanisms and explore making use of any other such mechanisms in other parts of the organisation or already established in other local organisations
- Partnerships – identify the effective clinical governance mechanisms already in use locally (usually in PCTs or mental health trusts) and help drive adoption of suitable mechanisms in services without these
- Partnerships – ensure the existence of, and participation by stakeholders in, a multi-agency group: with a remit to consider clinical governance for the drug treatment system as a whole and concerning the sharing of information and good practice
- Providers, commissioners or partnerships – consider the timetables of external assurance mechanisms (such as NTA treatment planning) and how these can mesh with local clinical governance processes
- Providers – consider the audit tools already available for drug treatment, for example, the NTA's guide to Auditing Drug Treatment (NTA, 2008a) and NICE's audit tools for its drug misuse 'Technology Appraisals' and 'Clinical Guidelines' (available at www.nice.org.uk).

7.2 Special considerations

Clinical governance within a single provider is relatively straightforward. But clinical governance within and across the many and varied services that make up the drug treatment system can be more complex. In developing clinical governance, special attention needs to be paid to, for example, the following:

- The interface between the local authority and drug services, especially in relation to the care of children affected by parental drug use and children using substances
- Mechanisms across a local drug partnership area
- Expectations on large third sector providers, which provide services in multiple partnership areas and may therefore experience demands to comply with different clinical governance systems and mechanisms
- Tier 4 services outside the partnership area and how their clinical governance is assured by purchasers, perhaps as part of regional commissioning arrangements.

8 Conclusion

Clinical governance is a systematic way of ensuring and improving quality of care. Until now, the extent to which it has been implemented in drug services has been variable, yet it has been a duty of both the NHS and services which it commissions, and independent healthcare, enshrined in law since 2004. It can no longer be seen as solely the domain of the NHS: non-NHS and social care services have an equal responsibility to provide the best possible care to their service users. It applies equally to all tiers involved in drug treatment, and is the task of primary as well as secondary care services.

Implementing clinical governance requires a whole system approach, from commissioners commissioning for quality and service providers implementing robust clinical governance frameworks and processes, to individual clinical teams and clinical and non-clinical staff working together to systematically evaluate and improve practice. It can also require a cultural shift: a collaborative and open approach and an environment in which there is recognition that blame is unhelpful and focusing on system change is the constructive approach required to truly improve client care. Strong leadership is key to achieving cultural change, and is the responsibility of, clinical leads, service managers and commissioners.

For partnerships and services that have not used this approach, a long-term view is recommended. Setting up the necessary structures and processes takes time. Cultural transformation may evolve only gradually. Taking an incremental approach is sensible: best practice advice is to benchmark current procedure and policy to start with and prioritise tasks according to clinical needs. Continual evaluation and monitoring through clinical audit cycles allows clinical governance processes to be built up year on year until they are woven integrally into every aspect of the work.

Service user and carer involvement may be invaluable in enabling prioritisation to be grounded in their needs and should be enlisted from the start. Keeping the focus on the service user will allow the best opportunity for genuine and visible improvement, allowing all involved to embrace it as a meaningful and highly constructive undertaking.

Experience of clinical governance, as illustrated in the local practice examples in appendix 1, shows that, when fully implemented, all involved – from commissioners to service providers and users – feel energised and motivated, and that they have gained a real tool with which they can drive change to achieve excellence in clinical care.

9 Appendix 1: Examples of local practice

This appendix contains four examples of how different organisations have responded to the need to implement clinical governance. They include:

- A partnership-commissioned voluntary sector community drug treatment provider and its integration into PCT clinical governance (9.1)
- A large mental health trust and its clinical governance across eight London boroughs (9.2)
- A large voluntary sector provider with a long history of clinical governance development (9.3)
- A local drug partnership overseeing clinical governance for the whole of their treatment system (9.4).

The illustrations are based upon information and opinions supplied by the organisations themselves and have not been verified by the NTA. They are intended only as examples of how some organisations have implemented clinical governance. Situations may vary from area to area and from organisation to organisation, and appropriate clinical governance implementation is for local determination.

9.1 PCT clinical governance for a voluntary sector drug treatment provider

Lifeline Kirklees

Kirklees DAAT has commissioned drug and alcohol treatment services for many years from Lifeline, a voluntary provider. Lifeline had no overarching corporate clinical governance policy. In 2006, the need to include Lifeline and other DAAT-commissioned services within the remit of the PCT clinical governance process was identified. A period of restitution lasting several months followed, with Lifeline Kirklees submitting some 57 policies, standard letters and forms.

The DAAT found the PCT clinical governance department to be very supportive, for instance they have provided useful tools and support around developing care pathways.

The PCT Clinical Governance Overview Group requires each policy to be presented in person, accompanied by a briefing paper written to the local standard format, which includes matching the policy to Standards for Better Health, and delineation of measurable performance indicators. To save time all the policies from DAAT-commissioned services are presented in two bundles (employment-related and practice-related).

The DAAT was already undertaking unrecognised clinical governance activity (for instance, audit) so arrangements were put in place to ensure the PCT's clinical governance lead is copied into all relevant documentation.

A further impact on the service was the need to gain clinical governance approval before any new therapies could be introduced into practice, following the Kerr-Haslam report (into how NHS services in Yorkshire dealt with concerns raised about two doctors' abuse of patients).

As a result of the process, in less than a year, Lifeline reported that:

- Commissioners had made progress towards being assured on many aspects of quality, and could identify others to be addressed
- The PCT had made significant progress towards fulfilling its statutory obligations to evidence compliance with SfBH, and improve annual ratings
- The service itself benefited from the structured approach to its quality initiatives, being able to identify policy gaps, demonstrate delivery of clinical quality already established and a feeling of improved integration with the local NHS

- Closer working relationships had been built up between the PCT and commissioners, and between commissioners and service managers. This led to improved recognition of each other's roles and a more coherent shared vision for patient care.

The DAAT reported that the management of clinical governance had been embedded in performance monitoring procedures, that the provider had established a regular clinical governance group of which clinical leads are core members, and that commissioners, clinical leads and senior provider managers have regular meetings to address clinical issues. The DAAT and provider, with support from the PCT clinical governance team, developed a clinical governance assurance reporting tool based on Standards for Better Health and the NTA/Healthcare Commission service review standards.

Commissioners and providers started the process looking at policies, procedures and care pathways. However the focus quickly shifted and was reported to now be much more comprehensive, with SfBH being used as an overarching quality assurance framework that brings together previously disparate activities and provides a mechanism for identifying gaps and addressing them.

9.2 Clinical governance across eight London boroughs

Central and North West London NHS Foundation Trust (formerly Central and North West London Mental Health NHS Trust)

The substance misuse service developed a quality framework and data management system in 1994 in response to the introduction of an injectable opioid treatment programme.

The framework comprised the original seven pillars (see appendix 3), three of their own, and national directives.

Eight clinical governance sub-committees were set up, covering clinical audit, risk management, infection control, medicines management, NICE implementation, research and development, therapeutics, and training and development. All linked with local clinical governance groups.

Problems identified by the trust included:

- **Resistance to change** was seen in organisations that had not been familiar with being accountable, and those with no clear leadership, permanent staffing or team structure. In contrast, those with strong leadership and teamworking adopted the framework readily
- **Loss of autonomy** – the trust expected cooperation with existing practice when joined by outside bodies, scrutinising and even rewriting policies that had already been ratified, Some non-statutory agencies perceived a threat at the idea of being 'taken over' by the NHS
- **Information sharing** – sharing protocols, serious untoward incidents reports, quality information and budget lines could be difficult due to lack of structures or because they were seen as too sensitive to share
- **Unwieldy procedure –** it was difficult to use a single process to assure governance for such a large and multifaceted organisation. Appointing chairs of shared clinical governance committees was problematic without approved qualifications for the role.

Solutions found by the trust included:

- **Clear leadership** had been hugely influential in the success of the clinical governance process
- **Staff engagement** – building friendly and caring relationships with staff had been helpful. In part this was achieved by meeting all staff regularly en masse to provide

simple, contemporary information, demonstrate the purpose of clinical governance and share experiences

- **Holding responsible people to account** – asking for an explanation of action plans and holding chairs to account for these
- **Local control –** each borough had its own clinical governance committee and the primary care and prison sector had its own managerial and governance arrangements. All were linked through an overarching strategic clinical governance committee chaired by the medical director.

Resource implications

Resources were needed for management courses for senior personnel and to implement quality improvements. Clinical governance was tied into commissioning meetings and commissioners usually responded.

Advantages of clinical governance reported by staff in the trust

- "The cardinal benefit has been the ability to form a culture that feels good. Staff know that they belong to this Directorate. It has removed any sense of 'poorer sister borough' and allowed for the expression of local need as well as local qualities."
- "The more people grasp it the more they want to be involved. This is exciting - as chair of a big committee, it is akin to conducting an orchestra of accomplished players."
- "The Trust has found that implementing clinical governance well has led to invitations to help out regions in trouble or need and this can assist with overheads and CIPs within the Directorate as a whole".

9.3 Large voluntary sector provider with long experience of developing clinical governance

Addaction

As an organisation Addaction had a long-held vision of wanting to monitor and demonstrate the quality of its services. The key drivers for this were:

- The vision and values of its previous chief executive
- Historically having had to be accountable to funders and commissioners due to its voluntary, non-statutory status
- Increasing interest in quality noticed when tendering for new business.

Accountability and monitoring against standards was a complex business in the early days as so many different bodies needed different (if only slightly) information, e.g. Best Value reviews by Local Authorities, commissioners, CSCI. However, joint commissioning resolved much of this multiplicity of standards and reporting systems.

Addaction's quality assurance framework was first established in 1995.

In 1999, when QuADS was published, some drug partnerships requested that Addaction services be compliant with the standards. In some areas partnerships commissioned external audits of the QuADS standards to see level of compliance. DrugScope acted as consultants and sent QuADS assessors in on request. However, there was no consistency of approach since some partnerships did not request it. Addaction's corporate response was:

- The organisation's quality assurance strategy encompassed the need for all projects to undertake QuADS self-assessment, in line with their quality values template
- The quality assurance strategy required all staff at every level to understand QuADS and to be involved in self-assessment.

The purpose of including all staff was to promote wider understanding of QuADS standards and to demystify them, thus ensuring that the standards were part of everyday work and not seen as something additional.

The next natural step was to look at the clinical governance framework: the quality assurance strategy and framework was reviewed against existing clinical governance principles and framework. As a result:

- Addaction's Clinical Governance Committee was set up
- The organisation established systems for examining clinical incidents and other parts of clinical governance.

An unexpected positive outcome from this was bringing more closely together the work of support services and senior managers, e.g. human resources operations (who had a remit for health and safety) and the quality assurance team.

When Standards for Better Health was launched, QuADS became less relevant.

As a result of its previous work on standards, Addaction felt well prepared in terms of audit for NTA/Healthcare Commission Service Reviews.

Reported benefits of quality assurance and clinical governance to Addaction:

- Ability to demonstrate quality to commissioners at tender and performance review and also to produce internal management information
- Ability to demonstrate quality to NTA/Healthcare Commission at Service Review
- Bringing together support services and senior management teams
- Involvement of all staff, which was empowering to more junior staff and allowed a bottom-up approach.

9.4 Local partnership overseeing clinical governance for its treatment system

Plymouth Drug and Alcohol Action Team

Context

In Plymouth, all services were managed by the voluntary sector, with statutory services seconding both statutory health and social care staff in to teams.

Plymouth Drug and Alcohol Action Team (Plymouth DAAT) needed assurance on the quality of the services they were commissioning after a period of massive local reorganisation and requirement to implement Models of Care.

In 2004, therefore, Plymouth DAAT appointed a clinical and service governance manager to its team to establish an inclusive governance framework committed to by all provider agencies.

Initial scoping

The governance manager found no specific models for drug and alcohol misuse agencies to follow and, in particular, none that cut across both health and social care, and both statutory and non-statutory services.

There were recurrent challenges in the everyday language of clinical governance: for instance, the traditional definition did not include social care and only covered the NHS, and the very word 'clinical' was not seen as sufficiently inclusive to encompass social care.

Performance management was a shared task between the governance manager and commissioner to ensure that performance change was managed in line with clinical governance standards.

In order to achieve maximum engagement with non-statutory agencies, it was felt important to avoid a top-down approach or anything that was derived solely from a health model of clinical governance. Therefore the standards had to be drawn up afresh, and in broad-based local consultation.

Underpinning the standards were the principles that they should concentrate on areas that directly impact on service users, with the main focus being on safety and effectiveness, and supporting systems.

Agreeing the framework

Key domains of the framework were drafted in the light of knowledge and experience of drug treatment services. Between four and ten standards were set for each domain according to local priorities.

This draft document was sent out for a very broad-based, inclusive three-month consultation. The fact that it referred throughout to SfBH made it far more acceptable to statutory healthcare organisations.

Implementing the governance process

A governance lead for each service was identified. These people needed to have the authority necessary to implement change in their organisations, and therefore tend to be chief executive or deputy chief executive level. Those from larger organisations could appoint domain-leads to report to them on specific areas such as audit, research and training.

A Service Governance Leads Group was then established, with monthly meetings chaired by the DAAT. Non-specialist agencies were also invited to send a representative, for example, police, probation, CAMHS etc, and were copied into all minutes.

Seven standards were chosen from the framework by the DAAT to be met within the first year. Service governance leads were invited to choose three more from the framework to address priorities of their own organisations. This had the further beneficial effects of allowing ownership of the process by all services, and introducing an audit and governance culture into services.

After a few months it became clear that a separate prescribing and pharmacy forum was needed because of the level of expertise and detail needed in dealing with these issues. This forum included prescribing specialists, pharmacists, and drug specialists from the police, and proved very effective in bringing about change and addressing poor practice.

Benefits of clinical governance

Practical:

- Local NTA better assured on quality and governance
- DAAT ownership of the process, real engagement of providers and partners
- All statutory and non-statutory services monitored against same standards and participate in common audit cycle
- PCT able to be easily assured on quality of Plymouth drug and alcohol services, as are SHA and DH
- Process anticipated recent NTA/Healthcare Commission Service Reviews – much of the work to bring services up to required standard had already been done
- Real improvements seen in harm reduction measures.

Organisational culture:

- Placing governance firmly at the heart of DAAT business – now addressed in all DAAT meetings
- Assisting whole-systems approach to managing change, because it made it safer to proceed

- Service users all involved in governance and all organisations had systems to engage them at all levels, from becoming trustees to signing care plans
- Cooperative relationships between organisations, e.g. on training and sharing policies
- Closer relationship with local health services.

Examples of specific improvements reported by the partnership

- Prescribing and pharmacy governance forum devised a system which enabled it to track poor prescribing and address this directly with prescriber
- Adoption of a common prescribing policy for the whole DAAT.

10 Appendix 2: Legal framework for clinical governance

10.1 Legislation

10.1.1 Health and Social Care Act 2008 and new arrangements

The Health and Social Care Act 2008 created a new, integrated regulator for health and adult social care: the Care Quality Commission. This brings together the functions of three previous bodies: the Healthcare Commission, the Commission for Social Care Inspection (CSCI) and the Mental Health Act Commission. The new regulator will register health and social care activities from April 2010, including:

- NHS trusts
- Services previously registered under the Care Standards Act 2000
- Any other services that the Department of Health may bring within the scope of registration.

Standards for Better Health (for healthcare) and national minimum standards (for social care) will be replaced by registration requirements, which will be assessed against compliance criteria. The framework that Standards for Better Health has provided for clinical governance is expected to be retained by many healthcare organisations and is likely to still be useful for drug treatment services.

Two key pieces of legislation prior to the 2008 act determined the structures and processes of clinical governance that guide current practice in drug treatment. These still have relevance during the 2009/10 transition year and are described below.

10.1.2 Care Standards Act 2000

This act applies to independent health and social care – whether private or voluntary sector. It established the principle of an autonomous statutory regulatory authority and legally obliges any independent service where treatment or nursing care is provided to register with the regulatory authority (formerly the Healthcare Commission, now the Care Quality Commission) and legislates for publication of national independent healthcare standards.

In 2009/10, CQC will continue to carry out the registration of health and adult social care providers under the Care Standards Act 2000.

10.1.3 Health and Social Care (Community Health and Standards) Act 2003

Health

This Act established a parallel legal framework for statutory sector health and social care. For healthcare, trust boards (i.e. mental health, primary care or acute trusts) that hold accountability – they must have arrangements to monitor and improve the healthcare they provide. Statutory health services are inspected by the Care Quality Commission against statutory standards frameworks (see section 11.2).

PCT model standing orders (DH, 2006) require the PCT and their chief executive officer to ensure that they explicitly commission for SfBH compliant care, and that they have appropriate mechanisms in place to monitor contract compliance.

Social care

The Act also covers social care for drug and alcohol treatment, but only where ‘nursing or personal care’ is provided, and not ‘healthcare’. For these organisations, registration and inspection is with the Commission for Social Care Inspection (CSCI).

Social care organisations which fall outside the Act do not have the same statutory duty for quality as that for healthcare, but all public sector bodies have a 'duty of care' enshrined in statute. For social care organisations there are now a variety of models of provision, varying between different local authorities, and this duty will be vested with whichever organisation they sit within, whether independent or statutory.

10.2 The legal framework for DH standards

10.2.1 Standards expected from healthcare organisations

Independent healthcare organisations continue to be obliged to meet Independent Healthcare National Minimum Standards Regulations (2002) – see section 11.3.

The following applies to public sector healthcare trusts, which are legally obliged to:

- Meet Standards for Better Health (SfBH)
- Continue to meet targets previously set by the Department of Health
- Work towards compliance with NICE guidelines and NSFs.

10.2.2 Standards expected from social care organisations

Social care organisations have to meet the National Minimum Standards Care Homes Regulations (2003) underpinned by the legal framework of the Care Standards Act 2000 and Care Home Regulations 2001 (see appendix 3).

10.3 Scrutiny by regulatory bodies

10.3.1 Scrutiny and inspection by the Care Quality Commission

The Care Quality Commission (CQC) was set up by the Health and Social Care Act 2008 to regulate the quality of health and adult social care and look after the interests of people detained under the Mental Health Act 1983. The Care Quality Commission brings together the work of its predecessors: the Commission for Social Care Inspection, the Healthcare Commission, and the Mental Health Act Commission.

2009/10 will be a year of transition in registration and inspection. The Care Quality Commission will begin the process of aligning its assessment of PCTs and councils from 2009/10.

In 2009/10, CQC will pull together evidence across PCT and council commissioning to provide integrated information for the Audit Commission-led Comprehensive Area Assessment (CAA) process. The periodic review is the only organisational assessment of NHS trusts and will be incorporated within the CAA process. CQC will also ensure that an appropriate profile for adult social care is reflected in the CAA process and that they publish a separate assessment of adult social care.

Reviews

The three types of review being undertaken by CQC in 2009/10 are:

- Periodic reviews assessing health and adult social care commissioning by primary care trusts (PCTs) and adult social care departments within councils
- Periodic reviews of health and adult social care providers, such as hospitals and care homes
- Special reviews and studies on particular aspects of health and adult social care.

The term ‘review’ describes CQC’s assessment of the quality of a service, using the information they hold about it, including people’s views. The review may also include a site visit to the service, sometimes called an inspection.

A special review or study is a one-off review to look at a specific topic or area and can be about virtually any aspect of health and adult social care. CQC will use special reviews and studies to report on how services are commissioned or provided across organisations, areas or care pathways, either across both health and adult social care or within one sector.

For independent providers of health and adult social care CQC will continue regular reviews in 2009/10 to ensure they are appropriately registered under the Care Standards Act 2000, in the same way as its predecessors.

Investigations

The Care Quality Commission undertakes thorough investigations in response to specific incidents, such as complaints or serious service failings, particularly where there are concerns for the safety of patients. An investigation involves developing an understanding of, and obtaining evidence on the reasons for a serious failing, and making recommendations to prevent recurrence. The Commission may carry out unannounced visits, or audits in specific cases.

Controlled drugs

The Care Quality Commission is responsible for regulating the management of controlled drugs by healthcare providers in England, using information in the annual self-declaration forms submitted by all NHS trusts and foundation trusts and monitoring the management of controlled drugs by independent healthcare providers.

The Care Quality Commission also takes part in local intelligence networks led by primary care trusts. These networks bring together organisations from the NHS and independent health and social care sectors, and other regulators including the Royal Pharmaceutical Society of Great Britain, and NHS counter-fraud services and police services.

The Care Quality Commission makes annual reports on how safely organisations manage controlled drugs and the findings of its national intelligence group on themes and trends in controlled drugs management.

Registration

From April 2010, new registration requirements for all health and social care providers will begin to come into force and we will be responsible for assuring people that they are complied with. Providers of health and adult social care services will need to meet the requirements of the Health and Social Care Act (Registration Requirements) Regulations 2009.

Registration is the process through which providers of services demonstrate that they meet an essential level of safety and quality before they can start to operate, and as they continue operating. The new system means that all registered social and health care providers will have a firm foundation on which to deliver care. The Care Quality Commission will expect providers to make improvements where they are needed to meet and sustain compliance with the Health and Social Care Act (Registration Requirements) Regulations 2009 and Care Quality Commission regulatory objectives as set out within that Act including encouraging improvement in services.

The Care Quality Commission will register providers that carry out specified activities to do with the provision of health or social care. These activities are set out in the Health and Social Care Act (Regulated Activities) Regulations 2009. Essential levels of safety and quality are set out in the Health and Social Care Act (Registration Requirements) Regulations 2009. All providers registered with CQC must comply with these requirements in order to become registered and then to remain registered.

10.3.2 Comprehensive Area Assessment

Comprehensive Area Assessment (CAA) looks at how well local services are working together to improve the quality of life for local people. It will make straightforward independent information available to people about their local services, helping them make informed choices and influence decisions.

Combining the perspectives of seven partner inspectorates, CAA will provide a joint assessment of outcomes for people in an area and a forward look at prospects for sustainable improvement.

CAA will look most at what matters locally. It may cover issues like improving access to healthcare, increasing the availability of affordable housing, reducing the fear of crime, improving educational achievement, attracting investment or reducing the area's carbon footprint. The issues assessed in each area will reflect local priorities for improving quality of life and protecting people at most risk of disadvantage.

10.3.3 Service Reviews

As part of its system of assessment for healthcare organisations, the Healthcare Commission undertook a number of Service (previously called 'Improvement') Reviews each year. A review was an in-depth examination of one aspect or 'theme' of care, and was carried out in every relevant organisation. Specific criteria were developed regarding the particular theme(s) chosen and used to make judgements about performance. The lowest performers were assisted to draw up an action plan to ensure standards are met.

The Healthcare Commission and NTA worked in partnership on substance misuse Service Reviews from 2005 to 2008. These examined:

- Care planning and prescribing (2005-6)
- Commissioning and harm minimisation (2006-7)
- Diversity and Tier 4 treatment (2007-8).

Information about the results of the Service Reviews can be found on the NTA website (www.nta.nhs.uk). The lowest scoring 10-12% of DATs were required to agree an action plan in conjunction with their regional NTA teams, who then monitored delivery of the plan.

11 Appendix 3: Frameworks and standards

11.1 Seven pillars model

The Seven Pillars of Clinical Governance model was devised by members of the NHS Clinical Governance Support Team in 1999. In this model the domains in which quality is to be assured are conceptualised as supporting pillars for a temple. The seven pillars in this model are:

- Risk management
- Clinical effectiveness
- Education, training and continuing personal and professional development
- Use of information
- Staffing and staff management
- Clinical audit
- Service user involvement.

In this model the apex of good clinical governance is the patient-professional partnership and the pillars are underpinned by a foundation of some of the cross-cutting themes of clinical governance: systems awareness, teamwork, communication, ownership and leadership.

Although the Clinical Governance Support Team closed in March 2008 information on the model is still available at www.cgsupport.nhs.uk.

11.2 Standards for Better Health

The Department of Health's Standards for Better Health (SfBH, often simply referred to as 'the Standards') were formally issued to the NHS in July 2004. They are more complex than the earlier models for several reasons:

- The Standards include financial governance and corporate governance in addition to 'pure' clinical governance
- The Standards address the need to balance current performance and future development by setting out two subsets within each domain: the core and the developmental standards:
  - Core standards relate to *existing provision,* deemed to be the minimum requirement
  - Developmental standards provide a framework for NHS bodies to plan the delivery of services that continue to improve in line with increasing patient expectations and the NHS Improvement Plan (DH, 2004b).
- SfBH were explicitly designed to synthesise an integrated framework from other national standards and reduce the burden of legislation on service providers. This process has created a new balance between types of standards which some have found problematic (Shaw, 2004).

The 44 standards are set out in seven domains, each of which contains several core standards and some developmental standards. Services which do not use SfBH at the outset may find it useful to map their standards to SfBH.

The Standards for Better Health (SfBH) can be found at the Heath Care Standards Unit website (www.hcsu.org.uk).

The World Class Commissioning assurance system via strategic health authorities will include some information previously covered in self-declarations against Standards for Better Health, and the new registration requirements in 2010/11 will incorporate and build on

relevant Standards for Better Health. Current Standards for Better Health will continue to be in force throughout 2009/10.

11.3 Independent healthcare standards

National minimum standards for independent healthcare were published in 2002 and independent healthcare providers were inspected against them by the Healthcare Commission. They comprise 32 core standards in eight domains and additional service-specific standards, including for mental health establishments. Mental heath service-specific standard M19 covers "treatment for addictions".

In drug misuse treatment, independent healthcare standards mostly apply to non-NHS detoxification units.

Independent Health Care: National Minimum Standards Regulations can be found at the Department of Health website (http://www.dh.gov.uk/assetRoot/04/07/83/67/04078367.pdf).

Independent healthcare standards are expected to be replaced by integrated health and social care registration requirements from 2010.

11.4 Social care standards

Within drug misuse treatment, national minimum standards for social care apply mainly to residential rehabilitation services registered as care homes (with or without nursing). The key standards are those contained in National Minimum Standards for Care Homes for Adults (18–65) and Supplementary Standards for Care Homes Accommodating Young People Aged 16 and 17 (DH, 2003). The standards cover eight domains, including socially-focused ones such as lifestyle and personal healthcare and support. The Commission for Social Care Inspection (CSCI) Guidance for Inspectors: Residential Services for Drug and Alcohol Addiction (CSCI, 2006) helps to clarify how each standard should be interpreted.

Drug care and treatment provided by social services will be covered by CQC's inspection and rating of how well councils serve adults who use social care services. Most children's services are now inspected by Ofsted.

National minimum standards for social care can be found at CQC's website (www.cqc.org.uk).

Social care standards are expected to be replaced by integrated health and social care registration requirements from 2010.

11.5 NTA/Healthcare Commission Service Review criteria

The 2005-8 joint Service Reviews by the NTA and Healthcare Commission specified criteria for the delivery of drug treatment, some of which may continue to be used by the NTA and Care Quality Commission in future review arrangements. They may also be used by services to review progress within their internal governance processes, including audit (see Auditing Drug Treatment, NTA 2008).

11.5.1 2005/06 review of community prescribing services, and care planning and care coordination

Community prescribing services

- Community prescribing services are commissioned in line with Models of Care for substance misuse treatment - promoting quality, efficiency and effectiveness in drug misuse treatment services (Models of Care) and Drug Misuse and Dependence - Guidelines on Clinical Management (the Clinical Guidelines).

- Service users have prompt, equitable and flexible access to community prescribing services.
- Service users have a personalised care plan that incorporates a comprehensive assessment of their physical, psychological, social and legal needs and preferences.
- Prescribing practice is in line with Models of Care.
- Community prescribing services have procedures in place to ensure controlled drugs are administered and managed in accordance with best practice.
- Community prescribing services are delivered by competent practitioners who are appropriately trained and supervised and work in a supported and managed environment.

Care planning and care coordination

- Service users are integrated partners in the entire treatment planning process and are fully informed about the range of treatment options, choice and access available.
- Service users have prompt, equitable and flexible access to an appropriate range of drug treatment services.
- Service users have a personalised care plan that incorporates a comprehensive assessment of their physical, psychological, social and legal needs and preferences.
- The pathways of service users through treatment are clear, coordinated and continuous.
- Services have systems in place to minimise client did not attend/drop out rates and support clients being retained in treatment.

11.5.2 2006/07 review of commissioning and systems management, and harm reduction

Commissioning and systems management

- Local commissioning partnerships have formal strategic partnerships with key stakeholders including health, social care, housing and employment services, drug treatment providers, and local drug user and carers.
- Local commissioning partnerships have a shared understanding of the local need for drug treatment, based upon annual needs assessment reports in line with a nationally agreed methodology. This methodology requires the needs assessment to profile the diversity of local need for drug treatment, including rates of morbidity and mortality (e.g. infection with blood borne viruses), the degree of treatment saturation or penetration, and impact of treatment on individual health, public health and offending.
- Local commissioning partnerships develop local drug treatment system plans annually in line with the Models of care update 2006 with focus on reducing harm to individuals and communities, improving clients' journeys through treatment, predicting client flow through local systems and improving the effectiveness of local drug systems.
- Local commissioning partnerships demonstrate best practice in handling public money, contracting with providers and monitoring service level agreements.
- Local commissioning partnerships performance manage local systems of drug treatment by using data and key performance indicators in partnership with local strategic partners and plans.
- Local commissioning partnerships are 'fit for purpose', have involvement from key stakeholders at an appropriate level of seniority and ensure commissioners are competent against national quality standards and other relevant professional frameworks.

Harm reduction

- Service users have prompt and flexible access to needle exchange services, vaccination, testing and treatment for blood borne viruses.
- Service providers deliver harm reduction interventions embedded in the whole treatment system.
- Service providers take action to reduce the number of drug-related deaths.
- Service providers have staff competent to deliver effective harm reduction services.

11.5.3 2007/08 review of diversity and Tier 4 services

Diversity

- Local commissioning partnerships ensure that the requirements of the Race Relations Amendment Act (2000), the Equality Act (2006) and the Disability Discrimination Act (2005) are complied with in the local treatment system.
- Local commissioning partnerships carry out needs assessments and treatment planning which includes the identification of and response to the needs of diverse populations.
- Local commissioning partnerships commission services to meet the needs of diverse populations.
- Service providers comply with the requirements of the Race Relations Amendment Act (2000), the Gender Equality Act (2006) and the Disability Discrimination Act (2005).
- Service providers ensure the delivery of provision and/or interventions that meet the needs of local diverse populations.
- Service providers plan and provide services in a way that considers and respects the views of service users and other service providers.

Tier 4

- Local commissioning partnerships have effective commissioning and/or purchasing processes for Tier 4 in-patient interventions.
- Local commissioning partnerships have effective commissioning and/or purchasing processes for Tier 4 residential rehabilitation interventions.
- Service users have prompt and flexible access to Tier 4 interventions.
- Services deliver Tier 4 interventions in line with an up-to-date evidence base that relates to the type of intervention or programme being delivered.
- Services provide Tier 4 interventions in a safe environment staffed by competent practitioners.

11.6 Equality duties

Recent legislation imposes duties on public authorities in relation to race, gender, disability, age, sexual orientation and religion or belief. These are summarised in table 4.

Group	**Legislation**	**Positive duty to …**		
		… eliminate unlawful discrimination	**… promote equality of opportunity**	**… promote good relations between communities**
Race	Race Relations (Amendment) Act 2000	✓	✓	✓

Gender	Equality Act 2006	✓	✓	
Disability	Disability Discrimination Act 2005	✓	✓	
Age	The Employment Equality (Age) Regulations 2006	✓*		
Sexual orientation	The Employment Equality (Sexual Orientation) Regulations 2003	✓*		
Religion or belief	The Employment Equality (Religion or Belief) Regulations 2003	✓*		

* in employment and training only

Table 4: Equality duties

All public authorities have a duty to implement race, gender and disability equality schemes. Statutory inspectorates, including the Care Quality Commission, have a duty to inspect and assure equality schemes. They must assess policies for relevance, monitor existing policies for adverse impact, and assess for potential adverse impact of proposed policies.

11.7 Quality in Alcohol and Drugs Services (QuADS)

Quality in Alcohol and Drugs Services (QuADS) standards (SCODA and Alcohol Concern, 1999) predate much of the current health service clinical governance infrastructure. QuADS standards concentrate on organisational and management quality. They are not clinical standards, in particular lacking specific requirements for safety or effectiveness in clinical treatments.

There is no statutory obligation to implement QuADS. Nonetheless it has historical value, as it was, for many services, the first set of quality standards by which they could assure themselves, or to which they were contractually obliged, and for commissioners the first framework against which they could ensure quality in services they commissioned.

QuADS can be found at Drugscope's website (www.drugscope.org.uk).

12 Appendix 4: Clinical audit

Effective clinical governance commonly relies on a clinical audit cycle in which topics to be addressed are decided (some of which may be externally imposed) and then:

- Criteria and standards are set (or externally required)
- Data is collected (or is provided from external sources) on how well the organisation is meeting the criteria
- The data is analysed to match performance against the expected standards
- Areas for improvement are identified and action agreed.

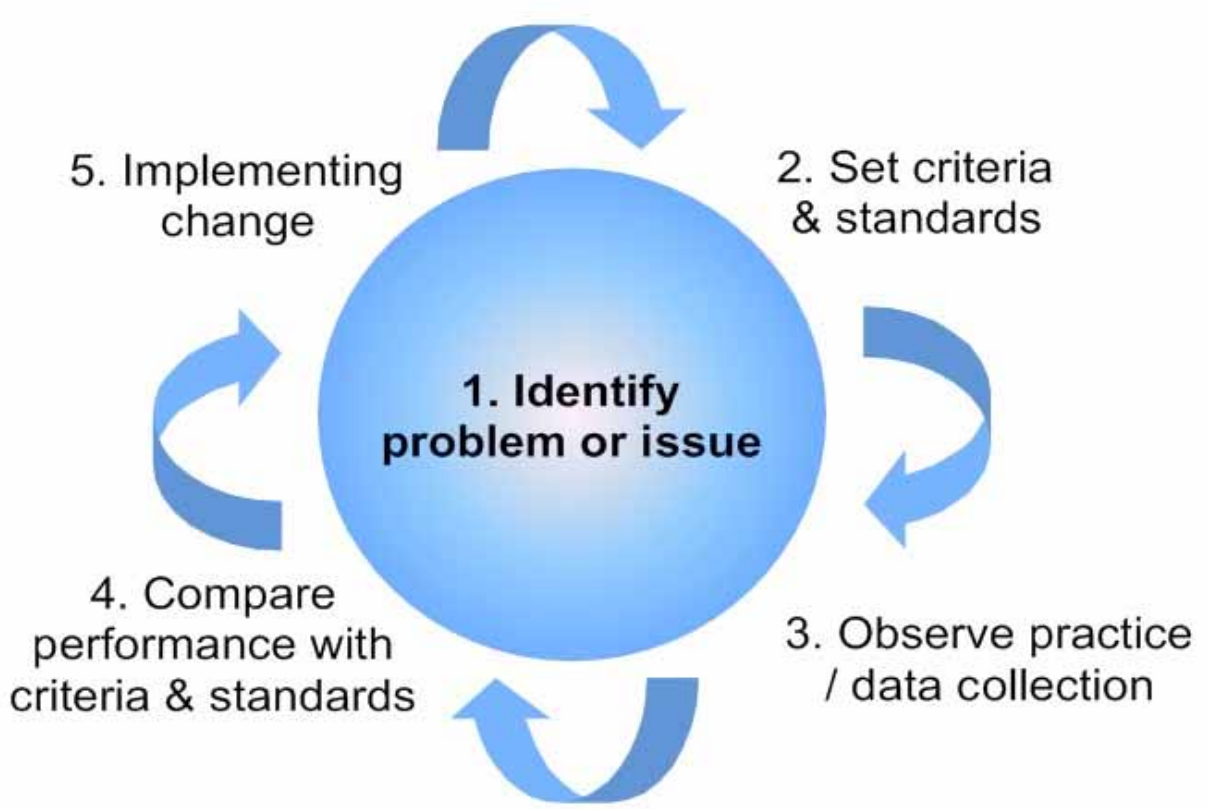


Figure 3: A simple audit cycle

Clinical audit acts as a driver for clinical governance because it provides evidence on the success (or otherwise) of interventions against agreed criteria and of changes needed. All clinical professional groups (doctors, nurses, pharmacists, psychologists, etc) can be expected to participate in clinical audit as part of their professional responsibilities for clinical governance.

Standards and criteria

Criteria and standards for drug treatment come from various sources. Generic statutory standards and other requirements include:

- Standards for Better Health, national minimum standards and new registration requirements
- Duties under the Race Relations (Amendment) Act 2000, the Equality Act 2006 and the Disability Discrimination Act 2005.

There are also sources of other, drug misuse-specific criteria and standards, including:

- NTA/Healthcare Commission Service Reviews (2005-2008)

- Needs assessments and annual treatment planning carried out to inform local priorities
- Occupational standards, including Drug and Alcohol National Occupational Standards (DANOS) and the NHS Knowledge and Skills Framework.

Some of these are described in more detail in appendix 3.

Data collection

There are two main methods of acquiring the evidence needed for assuring that audit standards are being met. These are: firstly, collating existing policies and protocols, which match the standards, and secondly, actively monitoring service delivery to establish whether audit standards are met.

There are a number of ways of monitoring service delivery in drug services. Acquiring data to analyse outcomes may be relatively easy if they are already being collected for some other purpose, and looking for opportunities to make intelligent use of existing data is advisable wherever possible. Examples of existing data which can be used include:

- National Drug Treatment Monitoring System (NDTMS), including Treatment Outcomes Profile (TOP) data
- NTA user satisfaction surveys and internal service user surveys
- Prescribing data
- Case notes, including care plans
- Staff training, supervision and appraisal records
- Serious untoward incident (SUI) reports and complaints.

It may also be necessary to set up systems to collect specific data on explicit criteria.

Assessment of performance and reporting

The assurance process examines the match between standards and delivery using a systematic evaluation and reporting process that:

- Maintains a continuing overview of delivery on the standards framework by examining the evidence collated in each domain and making a judgement about how well standards are being achieved
- Makes recommendations for service improvements
- Is responsible for making a declaration on this self-assessment to the appropriate inspectorate where relevant.

Key to comprehensive assurance process are structures which link all participants at all levels, from individuals, through service provider organisations, local partnerships, commissioners and inspectorates. Typically, specific groups with remits for particular clinical areas report assurance to the provider's clinical governance overview group, which in turn may report via commissioning bodies to the inspectorates. Crucially, communication must also flow downwards to teams and individuals involved, with findings and recommendations developed so that improvements can be made.

For organisations within the NHS 'umbrella' much of this structure already exists in trusts, and the challenge is to ensure that trust clinical governance leads are aware of their responsibilities and work closely with the provider to ensure clinical governance requirements are met. However, organisations providing care entirely within the independent sector will need to establish their own reporting and assurance processes.

13 Appendix 5: Clinical supervision

Clinical supervision (sometimes know as practice or specialist supervision) consists of a clinician meeting regularly with one or more other clinicians, not necessarily more senior, but normally with relevant clinical experience and competencies in supervision, to discuss casework and other professional issues in a structured way. It is intended to help the clinician to learn from their experience and improve their skills, and so improve client care. It is distinct from managerial supervision.

Clinical supervision is "a formal process of professional support and learning which enables individual practitioners to develop knowledge and competence, assume responsibility for their own practice and enhance consumer protection and safety of care in complex clinical situations" (DH, 1993). "In essence, clinical supervision is both a structure and a process through which the principles of reflective practice may be facilitated" (Cottrell, 2000).

Clinical supervision is not compulsory for every clinician but employers may require – and professional bodies may expect – specified staff to receive clinical supervision as a mechanism to ensure professional accountability as part of effective clinical governance.

Clinical supervision should monitor the employee's work with service users and maintain ethical and professional standards. It may be provided by the employee's manager, by professional peers in the same or another organisation or sometimes by independent clinical supervisors contracted in to provide supervision. Who provides it may not be important as long as the supervisor:

- Has relevant clinical experience with which to understand and reflect the supervisee's concerns
- Is competent in clinical supervision
- Is able to provide appropriate accountability for professionals such as doctors and nurses.

Clinical supervision may be one-to-one or in a group. Group supervision may demand fewer resources and provide a wider range of expertise and experience from which to draw learning. On the other hand, it may deter some individuals from being open about any difficulties they are experiencing.

The frequency of clinical supervision will vary depending on the experience and work setting of the employee but it should be an ongoing commitment, and should extend throughout an individual's career. Organisations may have a minimum requirement for the frequency of supervision: for example, one hour's clinical supervision per month or week depending on the level of experience of the employee. Newly-employed or recently-qualified employees may require more frequent clinical supervision. The nature and frequency of clinical supervision may need to be reviewed and adapted to reflect the changing role of a clinician, for example, a nurse or pharmacist working as a non-medical prescriber (NMP) may need to ensure additional clinical supervision is provided by a prescriber who has a high level of expertise in the NMP's prescribing area.

The roles of the supervisor and supervisee(s) should be clearly outlined in a supervision policy or separate clinical supervision policy. A record should be made that supervision has taken place and any materials shared in supervision must be held in confidence (including information about clients and the employee).

Talking about clinical work in a supportive environment can fulfil several different functions, which combine to fulfil the overall function of discussion and reflection in maintaining and enhancing the quality of service provision. Clinical supervision can:

- Help staff to generate ideas, which can be especially important if treatment has become 'stuck'

- Enable staff to check out that their own ways of working are not inconsistent with approaches within the service/profession, and gain validation for the work they are doing
- Allow staff to express some of the impact of therapeutic work on themselves, in a place where emotions can be contained and processed
- Provide the opportunity for staff to explore the possible impact of personal issues in their own lives on their therapeutic work with clients
- Provide the opportunity for advice and guidance, and potential understanding from a broader range of theoretical perspectives
- Provide an opportunity for staff to explore their existing knowledge, identify gaps, and be challenged to extend their knowledge and develop new approaches to practice.

(Adapted from Berkshire Healthcare NHS Foundation Trust, 2006)

14 Appendix 6: Sources of information and support for clinical governance

A large number of agencies can support services in implementing clinical governance. It is important to remember the local support that can be offered by the local drug partnership, PCT or MHT. In addition there are many national organisations whose input may be valuable. This appendix briefly describes these, firstly for general advice, and then for some specific clinical governance domains.

14.1 Drug treatment specific

National Treatment Agency

www.nta.nhs.uk

The NTA has a number of roles in relation to elements of clinical governance. These include:

- Ensuring partnership commissioning structures take full account of governance requirements of treatment systems
- Incorporation of unit costs / Value for Money in the commissioning process
- NDTMS and other treatment information governance.

14.2 General

14.2.1 Clinical governance implementation

NHS Clinical Governance Support Team (CGST)

http://collections.europarchive.org/tna/20081112112652/http:/www.cgsupport.nhs.uk/

Closed in March 2008 but website has been archived and remains a useful electronic library of catalogues, articles, case studies and other resources.

The Health Care Standards Unit (HCSU)

www.hcsu.org.uk

Works with the NHS and the Department of Health to ensure the Standards for Better Health are useful to staff, patients and other stakeholders.

The Information Centre for Health and Social Care

www.icservices.nhs.uk/clinicalgovernance

A special health authority which provided facts and figures to help health and social services to run effectively.

Clinical Governance Bulletin

www.rsmpress.co.uk/cgb.htm

The Royal Society of Medicine's online bulletin is a bi-monthly publication for clinicians and managers working in the NHS which highlights and disseminates best practice.

14.2.2 Safety and risk management

NHS Litigation Authority (NHSLA)

www.nhsla.com

A special health authority responsible for handling negligence claims made against NHS bodies in England, and works to prevent claims through an active risk management programme.

The NHSLA runs the Clinical Negligence Scheme for Trusts (CNST), which handles all clinical negligence claims against member NHS bodies. All NHS Trusts (including Foundation Trusts) and Primary Care Trusts (PCTs) in England currently belong to the scheme although membership is voluntary. While independent sector organisations cannot join CNST in their own right, they can benefit from cover when treating NHS patients via the membership of their referring PCT.

National Patient Safety Agency (NPSA)

www.npsa.nhs.uk

A special health authority with a remit to learn from patient safety incidents in the NHS. Central to this is the mandatory National Reporting and Learning System (NRLS) for adverse healthcare events and near misses in the NHS. The patient safety division is at www.npsa.nhs.uk/patientsafety. The NPSA's work also encompasses other areas, including:

- Ensuring research is carried out safely, through its responsibility for the National Research Ethics Service (www.nres.npsa.nhs.uk) (formerly COREC)
- Responsibility for the National Clinical Assessment Service (NCAS) (see below).

14.2.3 Clinical and cost effectiveness

Evidence base:

National Institute for Health and Clinical Excellence (NICE)

www.nice.org.uk

An independent organisation responsible for providing national guidance on the best practice cost-effective promotion of good health and the prevention and treatment of ill health based on available best quality evidence.

Clinical audit:

National Audit and Governance Group (NAGG)

www.nagg.co.uk

An umbrella organisation linking all the separate, sector specific, local and national clinical audit groups and associations through quarterly meetings and regular conferences. NAGG represents clinical audit at strategic level.

Professional education and training:

Royal College of General Practitioners (RCGP) Substance Misuse Unit (SMU)

www.rcgp.org.uk

The RCGP sets standards for the training and qualifying examinations for GPs, as well as a programme of postgraduate Continuing Professional Development. The SMU, a faculty of the RCGP, educates and certifies GPs and other disciplines in management of drug and alcohol misuse through its certificate programme, and issues guidance on specific areas of drug misuse treatment.

Royal College of Psychiatrists (RCPsych) Faculty for Addictions

www.rcpsych.ac.uk/college/faculties/addictions.aspx

The Faculty is committed to education and training, setting clearly defined standards for future addiction specialists, influencing the training of medical students and other doctors.

British Psychological Society (BPS) Division of Clinical Psychology – Faculty for Addictions

www.bps.org.uk/dcp-addiction.cfm

The Faculty has a programme of CPD events as well as defining the standards and competencies for addiction psychology specialists and providing BPS national assessors for consultant psychologist appointments in specialist addiction posts.

14.2.4 Governance

Professional and performance issues:

National Clinical Assessment Service (NCAS)

www.ncas.npsa.nhs.uk

Provides confidential advice and support to the NHS in situations where the performance of doctors (and dentists) is giving cause for concern.

General Medical Council (GMC)

www.gmc-uk.org

The regulator of the medical profession. Their purpose is to protect, promote and maintain the health and safety of the community by ensuring proper standards in the practice of medicine. Registration with the GMC is mandatory for all medical practitioners in the UK.

Nursing and Midwifery Council (NMC)

www.nmc-uk.org

An organisation set up by Parliament to protect the public by ensuring that nurses and midwives provide high standards of care. To achieve its aims, NMC functions include: maintaining a register, setting standards for conduct, performance and ethics and considering allegations of misconduct, lack of competence or unfitness to practise due to ill health.

British Psychological Society (BPS)

www.bps.org.uk

The representative body for psychology and psychologists in the UK. It has a national responsibility for the development, promotion and application of psychology for the public good. It provides accreditation and standards for individuals, and maintains a register and licensing of psychologists as practitioners.

Royal Pharmaceutical Society of Great Britain (RPSGB)

www.rpsgb.org.uk

The professional and regulatory body for pharmacists and pharmacy technicians in England, Scotland and Wales. Professional regulation functions include: registration, setting professional standards, and dealing with performance and misconduct issues

General Social Care Council

www.gscc.org.uk

The workforce regulator and guardian of standards for the social care workforce in England, established in October 2001 under the Care Standards Act 2000.

Health Professions Council (for Allied Health Professions)

www.hpc-uk.org

A statutory regulator that works to protect the health and well-being of people using the services of the health professionals registered with us. The HPC currently registers

professionals from 13 disciplines, the most relevant of which are Arts therapists and occupational therapists.

Information governance:

Information Commission

www.ico.gov.uk

Promotes access to official information and protects personal information by promoting good practice, ruling on eligible complaints, providing information to individuals and organisations, and taking appropriate action when the law is broken.

Department of Health policy and guidance information governance section

www.dh.gov.uk/PolicyAndGuidance/InformationPolicy/fs/en

The 'Policy and guidance' section of the DH website has pages on health and social care information governance with links to many useful publications and related organisations.

Connecting for Health

www.connectingforhealth.nhs.uk/systemsandservices/infogov/policy

Oversees development of new NHS computer systems and services that link GPs and community services to hospitals. There is a very useful information governance section accessible from the 'systems and services' section of their website.

15 Glossary

Clinical governance is 'a framework through which … organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish' (DH, 1998)

Clinical supervision is about promoting the development of therapeutic competence and covers clinical work, professional standards, personal growth and development, and evaluation of work performance. It is distinct from managerial supervision, although both may be carried out by the same person.

Clinical audit is a process to monitor and improve client care and outcomes. It involves evaluation against explicit criteria, and aims to determine whether guidelines are being followed and standards met, and whether best practice is being applied. It is distinct from research, which is conducted with the aim of generating new knowledge that determines what best practice is.

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